UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA SHERIFFS' PENSION AND RELIEF FUND, derivatively, on behalf of PFIZER INC., Plaintiff, v. DENNIS A. AUSIELLO; MICHAEL S. BROWN; M. ANTHONY BURNS; ROBERT N. BURT; W. DON CORNWELL; WILLIAM H. GRAY III; CONSTANCE J. HORNER; JAMES M. KILTS; JEFFREY B. KINDLER; GEORGE A. LORCH; DANA G. MEAD; SUZANNE NORA JOHNSON; WILLIAM C. STEERE; JR.; DOUGLAS M. LANKLER; FRANK. A. D'AMELIO; IAN C. READ; and JOSEPH M. FECZKO, Defendants, and PFIZER INC., Nominal Defendant.	C.A. No. 09 CIV 8042 **ECF CASE** **VERIFIED DERIVATIVE COMPLAINT** **JURY TRIAL DEMANDED**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Louisiana Sheriffs' Pension and Relief Fund ("Plaintiff'), by and through its undersigned attorneys, hereby submits this Verified Shareholder Derivative Complaint (the "Complaint") for the benefit of nominal defendant Pfizer Inc. ("Pfizer" or the "Company"), against certain current and former members of its Board of Directors (the "Board") and executive officers seeking to remedy defendants' breaches of fiduciary duties, violations of the federal proxy law, and unjust enrichment from 2002 to the present (the "Relevant Period").

I. INTRODUCTION

1. This case arises from misconduct resulting in what the U.S. Department of Justice ("DOJ") described as "the largest criminal fine ever imposed in the United States for any matter" and the "largest civil fraud settlement in history against a pharmaceutical company." The $2.3 billion settlement, announced on September 2, 2009, involved Pfizer's fraudulent marketing of at least 13 drugs over the course of almost 8 years. Pfizer's prolonged and widespread illegal marketing and promotion of pharmaceutical drugs required these historic penalties. The U.S. Attorney for the District of Massachusetts concluded in announcing the settlement, "***[t]he size and seriousness of this resolution . . . reflect the seriousness and scope of Pfizer's crimes***, Pfizer violated the law over an extensive time period."[1]

2. As explained herein and will be shown at trial, the criminal conduct warranting this unprecedented punishment is not the work of a rogue employee or business division outside the purview of Pfizer's board and senior management. Rather, Pfizer's directors were clearly informed about, allowed and encouraged this pervasive criminal behavior. Indeed, Pfizer's violations represent a pattern and practice that illustrates the Board's consciously wrongful attitude towards known criminal behavior by Pfizer employees throughout the Company and reflect the fact that Pfizer's illegal marketing of its drugs was part of a calculated strategy to put short term profit ahead of the needs of patients and the long-term interests of Pfizer shareholders. The Board of Directors and certain senior executives who are at the heart of Pfizer's criminal conduct, described below, must be held accountable.

3. Pfizer's historic $2.3 billion settlement follows years of rampant illegal conduct

[1] Emphasis has been added unless otherwise indicated.

and numerous prior regulatory and enforcement actions known to the Company's Board of Directors and its senior executives. This is Pfizer's fourth multi-million dollar fine, and third criminal guilty plea, for illegal marketing since 2002. The U.S. Attorney himself attributed the severity of the fines to "Pfizer's recidivism." He explained that "at the very same time Pfizer was in our office negotiating and resolving [prior] allegations of criminal conduct . . . Pfizer was itself in its other operations violating those very same laws. ***Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated.***"

4. In 2002, Pfizer and another wholly owned subsidiary, the Warner Lambert Company ("Warner Lambert"), agreed to pay $49 million to settle allegations that the Company had paid illegal kickbacks to health professionals for prescribing Pfizer's anti-cholesterol drug "Lipitor." Regulators insisted that Pfizer enter into a "Corporate Integrity Agreement" that required Pfizer's Compliance Officer to "make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer" and provided that he or she was also "authorized to report on such matters to the Board of Directors at any time." Notwithstanding the 2002 Corporate Integrity Agreement, Pfizer's Board allowed the Company to continue its practice of paying illegal kickbacks to encourage improper prescriptions for nine other drugs.

5. In 2004, another Pfizer subsidiary pled guilty to criminal charges for misbranding Pfizer drug "Neurontin," including the illegal and deceptive promotion of off-label uses and doses. To settle the charges, Pfizer agreed to pay a $240 million criminal fine, which the DOJ noted at the time was "***the second largest criminal fine ever imposed in a health care fraud prosecution***." Pfizer also paid $190 million to resolve related civil False Claims Act liabilities, and agreed to enter into another "Corporate Integrity Agreement" aimed at preventing

future violation. This Corporate Integrity Agreement again required the Compliance Officer to "make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer" and authorized them to make such reports "at any time." The agreement also required Pfizer's Chief Compliance Officer and Pfizer's Deputy Compliance Officer to directly inform the Board of any reported violations and the status of Pfizer's compliance with FDA requirements, Federal healthcare program requirements and the Federal anti-kickback statute.

6. In 2007, Pfizer again met criminal sanctions for illegally marketing its products. Pfizer subsidiary, Pharmacia, entered into a criminal guilty plea for the illegal promotion and sales practices of Pfizer drug Genotropin, a human growth hormone (anabolic steroid). To settle the charges, Pfizer entered into a deferred prosecution agreement with the U.S. Attorneys' Office in Massachusetts and agreed to pay $34.6 million in criminal fines.

7. Pursuant to the Corporate Integrity Agreements, Defendants were continually advised about the status of Pfizer's compliance (and non-compliance) with federal regulations. The widespread violations of federal law nevertheless continued unabated under their supervision and management. This could only be the result of Defendants' encouragement or their conscious disregard of reports that Pfizer was breaking the law in breach of their duties of good faith and loyalty to Pfizer and its shareholders. As a former Pfizer sales representative has publicly stated "[t]he whole culture of Pfizer is driven by sales, and if you didn't sell drugs illegally, you were not seen as a team player."

8. The fact that Pfizer had been operated, in effect, as an ongoing criminal enterprise, was not hidden from Pfizer's Board of Directors, who repeatedly and knowingly disregarded numerous red flags demonstrating the Company's wrongdoing, including:

a. Reports made by Pfizer's Chief Compliance Officer directly to the Board regarding Pfizer's widespread violations of federal law involving numerous Pfizer drugs pursuant to Pfizer's code of conduct and the 2002 and 2004 Corporate Integrity Agreements;

b. Reports made by numerous Pfizer employees to Pfizer's Chief Compliance Officer regarding widespread illegal misconduct pursuant to an internal disclosure program required by Pfizer's Corporate Integrity Agreements, leading to improper retaliation and to 11 qui tam "whistleblower" lawsuits," nine of which the U.S. government joined and were incorporated in the $2.3 billion settlement;

c. Reports of an FDA Warning Letter directly to Pfizer's Chairman and CEO and several notices of violation notifying Pfizer of the very conduct covered by the $2.3 billion settlement, and that such practices violated federal law, which also were reported to the Board pursuant to Pfizer's Code of Conduct and the 2002 and 2004 Corporate Integrity Agreements; and

d. Reports of misconduct underlying the 2002, 2004 and 2007 criminal and civil settlements and penalties regarding illegal marketing practices involving Lipitor, Neurontin, and Genotropin.

9. Pfizer's repeat-offender status, the numerous Pfizer drugs involved, and ***the habitual nature and similarity of its crimes throughout the Company*** have caused tremendous damage to Pfizer's shareholders. This damage includes not only the $2.3 billion in settlement payouts, but also exposure to damages and legal expenses from numerous consumer actions for illegally and deceptively marketing Pfizer drugs to doctors, personal injury actions by individuals who were harmed by the off-label use or dosages, at least 11 whistleblower lawsuits filed by employees seeking to expose this wrongdoing, and the loss of Pfizer's reputation from the world's preeminent pharmaceutical company to among the worst violators of federal law. Immediate intervention is also needed because, as industry sources have explained, the continuing and future violations could cause Pfizer's debarment from federal programs, which would be a "death knell" causing Pfizer to lose most of its business.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C.

1332(a)(1) because complete diversity exists between Plaintiff and each Defendant, and the amount in controversy exceeds $75,000. This Court also has jurisdiction of this action under federal question jurisdiction pursuant to 28 U.S.C. § 1331 because this is a civil action arising under the laws of the United States. In addition, this Court has exclusive jurisdiction over this action pursuant to Section 27 of the Securities Exchange Act, 15 U.S.C. §§ 78aa, because this action asserts claims under Section 14(a) of the Exchange Act, 15 U.S.C. §78n(a), and has supplemental jurisdiction over the non-federal claims asserted herein under 28 U.S.C. § 1367(a). This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

11. Venue is proper in this District pursuant to 28 U.S. §1391(a). Substantial acts in furtherance of the alleged wrongdoing and/or their effects have occurred within this District, and Nominal Defendant Pfizer, Inc.'s headquarters are in New York, New York.

III. THE PARTIES

12. Plaintiff Louisiana Sheriffs' Pension and Relief Fund ("Louisiana Sheriffs") is a defined-benefit pension fund for police officers in the State of Louisiana. Louisiana Sheriffs is a current shareholder of Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action. Louisiana Sheriffs is a citizen of Louisiana.

13. Nominal defendant Pfizer is a Delaware corporation headquartered in New York, New York. Pfizer describes itself as "the world's largest research-based biomedical and pharmaceutical company." Pfizer employs more than 80,000 people in over 150 countries. At all relevant times herein, Pfizer distributed or directed the distribution of pharmaceutical drugs to all fifty states and the District of Columbia.

14. Defendant Dennis A. Ausiello ("Ausiello") has served as a director of the

Corporate Governance Committee during the Relevant Period. Since 2002, Ausiello received more than $573,000 for his service as a director of the Company. On information and belief, Ausiello is a citizen of Massachusetts.

15. Defendant Michael S. Brown ("Brown") has served as a director of the Company since 1996. In addition, Brown served as a member of the Corporate Governance Committee during the Relevant Period. Since 2002, Brown received more than $1,200,000 for his service as a director of the Company. On information and belief, Brown is a citizen of Texas.

16. Defendant M. Anthony Burns ("Burns") has served as a director of the Company since 1998. In addition, Burns has served as a member of both the Executive Committee and the Audit Committee during the Relevant Period. Since 2002, Burns received more than $1,000,000 for his service as a director of the Company. On information and belief, Burns is a citizen of Florida.

17. Defendant Robert N. Burt ("Burt") has served as a director of the Company since 2000. In addition, during the Relevant Period, Burt served as a member of the Audit Committee and of the Board's and Compensation Committee. Since 2002, Burt received more than $1,000,000 for his service as a director of the Company. On information and belief, Burt is a citizen of Illinois.

18. Defendant W. Don Cornwell ("Cornwell") has served as a director of the Company since 1997. In addition, Cornwell has served as a chair of the Audit Committee during the Relevant Period. Since 2002, Cornwell received more than $1,000,000 for his service as a director of the Company. On information and belief, Cornwell is a citizen of New York.

19. Defendant William H. Gray III ("Gray") has served as a director of the Company since 2000. In addition, Gray served as a member of the Corporate Governance Committee

during the Relevant Period. Since 2002, Gray received more than $975,000 for his service as a director of the Company. On information and belief, Gray is a citizen of Florida.

20. Defendant Constance J. Horner ("Horner") has served as a director of the Company since 1993. In addition, Horner served as a chair of the Corporate Governance Committee and a member of the Executive Committee during the Relevant Period. Since 2002, Horner received more than $1,000,000 for her service as a director of the Company. On information and belief, Horner is a citizen of Virginia.

21. Defendant James M. Kilts ("Kilts") has served as a director of the Company since 2007. In addition, Kilts served as a member of the Compensation Committee during the Relevant Period. In 2007 and 2008, Kilts received more than $365,000 for his service as a director of the Company. On information and belief, Kilts is a citizen of New York.

22. Defendant Jeffrey B. Kindler ("Kindler") has served as the Company's Chief Executive Officer ("CEO") since July 31, 2006. Before becoming Pfizer's CEO, Kindler served as Pfizer's General Counsel and Chief Compliance Officer for part of the Relevant Period. In addition, Kindler has served as a director of the Company since July 2006 and as Chairman of the Board since December 2006. In addition, Kindler served as a member of the Executive Committee during part of the Relevant Period. In 2008, Kindler received more than $13 million for his service to the Company, including a salary of $1,575,000, stock awards of $4,715,947, stock options worth $3,281,916, non-equity incentive compensation of $3,000,000, and non-qualified deferred compensation earnings of $759,298. Since 2006, Kindler has received more than $33 million for his service to Pfizer. On information and belief, Kilts is a citizen of Connecticut.

23. Defendant George A. Lorch ("Lorch") has served as a director of the Company

since 2000. Additionally, during the Relevant Period Lorch served as a member of the Compensation Committee. Since 2002, Lorch received more than $1,000,000 for his service as a director of the Company. On information and belief, Lorch is a citizen of Florida.

24. Defendant Suzanne Nora Johnson ("Johnson") has served as a director of the Company since 2007. Additionally, Johnson has served as a member of the Audit Committee during the Relevant Period. In 2007 and 2008, Johnson received more than $375,000 for her service as a director of the Company. On information and belief, Johnson is a citizen of California.

25. Defendant Dana G. Mead ("Mead") has served as a director of the Company since 1998. Additionally, during the Relevant Period Mead served as Chair of the Compensation Committee. Since 2002, Mead received more than $1,000,000 for his service as a director of the Company. On information and belief, Mead is a citizen of Massachusetts.

26. Defendant William C. Steere, Jr. ("Steere") has served as a director of the Company since 1987. Additionally, Steere has served as Chairman Emeritus of the Company since July 2001, as Chairman of the Board from 1992 to April 2001 and CEO from 1991 to 2000. During the Relevant Period Steere also served on the Corporate Governance Committee. Since 2002, Steere received more than $840,000 for his service to the Company. On information and belief, Steere is a citizen of Florida.

27. Defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, and Steere are collectively referred to as the "Director Defendants."

28. Defendant Frank A. D'Amelio ("D'Amelio") has served as Chief Financial Officer ("CFO") of the Company since September 2007. In 2008, D'Amelio received more than $8.1 million for his service to the Company. On information and belief, D'Amelio is a citizen of

New Jersey.

29. Defendant Joseph M. Feczko ("Feczko") served as the Company's Chief Medical Officer from 2006 until 2009. On information and belief, Feczko is a citizen of Connecticut.

30. Defendant Douglas M. Lankler ("Lankler") has served as Senior Corporate Counsel, Senior Vice President and Chief Compliance Officer of Pfizer during part of the Relevant Period. He is a signatory to the 2004 and 2009 Corporate Integrity Agreements. On information and belief, Lankler is a citizen of New York.

31. Defendant Ian Read ("Read") has served as Senior Vice President and President, Worldwide Pharmaceutical Operations for the Company during the Relevant Period. In 2008, Read received more than $6.8 million for his service to the Company. On information and belief, Read is a citizen of Connecticut.

32. Defendants D'Amelio, Feczko, Kindler, Lankler and Read are collectively referred to as the "Executive Defendants."

33. The Director Defendants and the Executive Defendants are collectively referred to as "Defendants."

34. Non-party Stephen W. Sanger ("Sanger") has served as a director of the Company since February 2009.

IV. FACTUAL BACKGROUND

A. Background on Pfizer and the Regulation of Its Business

35. Pfizer is one of the world's largest pharmaceutical companies. Directly and through wholly-owned subsidiaries such as Pharmacia and Warner Lambert, Pfizer engages in the business of manufacturing, marketing and selling of prescription drugs and other products for the prevention, diagnosis and treatment of illness and afflictions in the United States and the rest of the world. At the relevant times, Pfizer's products included Aricept, Bextra, Lipitor, Lyrica,

Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyvox, Zyrtec and Zyvox. A number of those products are "blockbuster drugs," meaning that they earned Pfizer more than $1 billion per year in revenue. Examples are Neurontin ($1.7 billion in 2001), Bextra ($1.3 billion in 2003), Celebrex ($2.4 billion in 2008), Viagra ($1.9 billion in 2008) and Lipitor ($12.4 billion in 2008). During fiscal year 2008, Pfizer's business generated $8.1 billion in profit.

36. Pfizer's business is the focus of extensive regulation and oversight by the FDA, which regulates the development, manufacture, and distribution of drugs in the United States. Drug manufacturers like Pfizer must establish the efficacy and safety of drugs to the satisfaction of the FDA before they can be legally marketed for commercial use.

37. When the FDA approves a drug, it does so for a specific use and dosage, and all the relevant information regarding the limitations of the FDA's approval is included on the drug's label. Any use of a drug that is inconsistent with or outside the scope of the drug's FDA-approved label is considered an "off-label" use.

38. Although doctors may prescribe drugs off-label if medically appropriate, the Federal Food, Drug and Cosmetics Act ("FDCA") makes it illegal for drug manufacturers to promote or market a drug for any use outside the product's labeling—*i.e.*, Pfizer cannot market or promote drugs for off-label use. *See* 21 U.S.C. §§ 333, 352. Under the FDCA, a product promoted for off-label use is "misbranded" if it has inadequate directions for the unapproved use or because the manufacturer has provided "false and misleading" information regarding the product. *See* 21 U.S.C. § 352. Further, because a new drug may not be approved for marketing unless it has shown to be safe and effective for its intended use to the satisfaction of the FDA, a manufacturer must resubmit its existing drugs for FDA approval any time it wishes to promote a new "intended use" not listed on the original FDA approved labeling. Such unapproved uses are

considered "off-label," and a manufacturer that promotes a drug for off-label uses violates the FDCA proscription on misbranding by failing to provide adequate directions for the off-label use.

39. Pharmaceutical companies that violate the FDCA prohibition against misbranding and introducing "new" uses for approved drugs may be subject to potentially severe penalties, including criminal prosecution, injunctions and the seizure of misbranded or unapproved new drugs. Because misbranding and off-label promotion improperly induces doctors to prescribe drugs for uses and dosages that are not approved by the FDA but may still improperly have been reimbursed by Federal healthcare programs such as Medicaid and Medicare, Pharmaceutical companies may also be subject to liability under the civil False Claims Act and the Federal anti-kickback statute. *See* 31 U.S.C. § 3729; 42 U.S.C. § 1320a-7b. The False Claims Act also contains whistleblower—or *qui tam*—provisions that allow individuals who are aware of fraud against the government to file suit on the government's behalf and receive a portion of the recovered funds.

40. Pharmaceutical companies that are convicted of a crime under the FDCA may be subject to exclusion or "debarment" from Federal healthcare programs. Such federal debarment would result in untold damage to the Company and its shareholders because Medicaid and Medicare patients would in that case be presented with the choice of paying the Pfizer for drugs out of pocket, finding an alternative drug with the same use, or foregoing treatment altogether. *See* 42 U.S.C. § 1320a-7.

B. Pfizer's Extensive History of Illegally Marketing Products for Off-Label Uses and of Paying Illegal Kickbacks

1. 2002 Settlement for Illegally Marketing Lipitor

41. Lipitor is a medication that reduces low-density lipoprotein cholesterol and

overall cholesterol in the blood. Lowering cholesterol can help prevent heart disease, strokes and vascular disease. Financially, Lipitor has been one of Pfizer's most successful drugs, ranking among the world's most profitable drugs of the past decade.

42. In 2002, Pfizer's wholly-owned subsidiary, Warner Lambert, settled charges under the civil False Claims Act alleging that it had illegally concealed cash discounts given to a managed care organization in New Orleans called the Ochsner Health Plan ("Ochsner"). In exchange for these concealed discounts, Ochsner agreed to extend an unlawful *quid pro quo* in the form of an "unrestricted formulary status to Lipitor in order to encourage Ochsner plan doctors to write Lipitor prescriptions for Ochnser plan beneficiaries." As a result of the illegal non-disclosure of those discounts, Warner Lambert was alleged to have retained $20 million in Medicaid rebates that it owed to the Medicaid program.

43. To settle the charges that it had improperly overcharged the Medicaid program, Pfizer agreed to pay $49 million and to enter into a five-year corporate integrity agreement with the Department of Health and Human Services' Office of Inspector General (the "2002 CIA"). In the preamble, Pfizer represented that it had already *voluntarily* implemented compliance measures, including "the appointment of a Compliance Committee, a Disclosure Program … and regular training" of "all employees of the Pfizer Pharmaceuticals Group located in the United States whose job responsibilities directly related to the promotion of prescription drug products to managed care facilities" and "those persons of Pfizer's contract sales force whose job responsibilities directly related to Managed Care Contracting."

44. The 2002 CIA also required Pfizer to maintain a compliance program and to employ a Compliance Officer as member of senior management who "***shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of***

Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and shall be authorized to report on such matters to the Board of Directors any time."

45. In the 2002 CIA, Pfizer also agreed within 120 days to "implement written policies and procedures regarding the operation of the Pfizer's Compliance Program, and its compliance with Federal health care program requirements." At a minimum, those policies and procedures were required to address, among other things, "promotional practices that conform with all applicable Federal health care program requirements, including but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b."

46. As set forth below, Pfizer's Board allowed violations of Federal law to continue unabated after Pfizer agreed to the terms and conditions of the 2002 CIA.

2. 2004 Settlement and Criminal Fine for Illegally Marketing Neurontin

47. Neurontin is an anticonvulsant medication that affects chemicals and nerves in the body that cause seizures. In the U.S., Neurontin is manufactured and sold by Warner Lambert, a wholly-owned subsidiary of Pfizer.

48. The FDA approved the use of Neurontin for the management of post-herpetic neuralgia (pain resulting from damage caused by shingles or herpes zoster) in adults and to control epileptic seizures of adults if used in conjunction with another drug. The FDA approved doses ranging from 900 mg to 1800 mg per day. Neurontin is a drug with dangerous side effects, even when it is administered for an approved use and at an approved dosage.[2]

49. In 1997, Warner Lambert formally applied to the FDA to change Neurontin's

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[2] On January 31, 2008, the FDA sent out an alert entitled "Serious Health Risks with Antiepileptic Drugs" to alert health care professionals and consumers that a review of 11 antiepileptic drug studies showed that patients taking anti-epileptics such as Neurontin "have about twice the risk of suicidal thoughts and behaviors, compared with patients receiving an inactive substance (pacebo)."

labeling to include a mono-therapy indication for epilepsy seizures. The FDA rejected this application because Warner Lambert failed to demonstrate efficacy. The FDA also did not approve the prescription of Neurontin for use as a general pain medication or for the treatment of bipolar disorder, depression, migraine, or attention deficit disorder. Warner Lambert nevertheless began to promote Neurontin for off-label uses and dosages, without knowing whether it was medically safe to do so, for: (i) off-label dosages exceeding 1800 mg per day; (ii) use as an epilepsy monotherapy; (iii) use as a general pain medication; and (iv) use as treatment of bipolar disorder, depression, migraine, and attention deficit disorder.

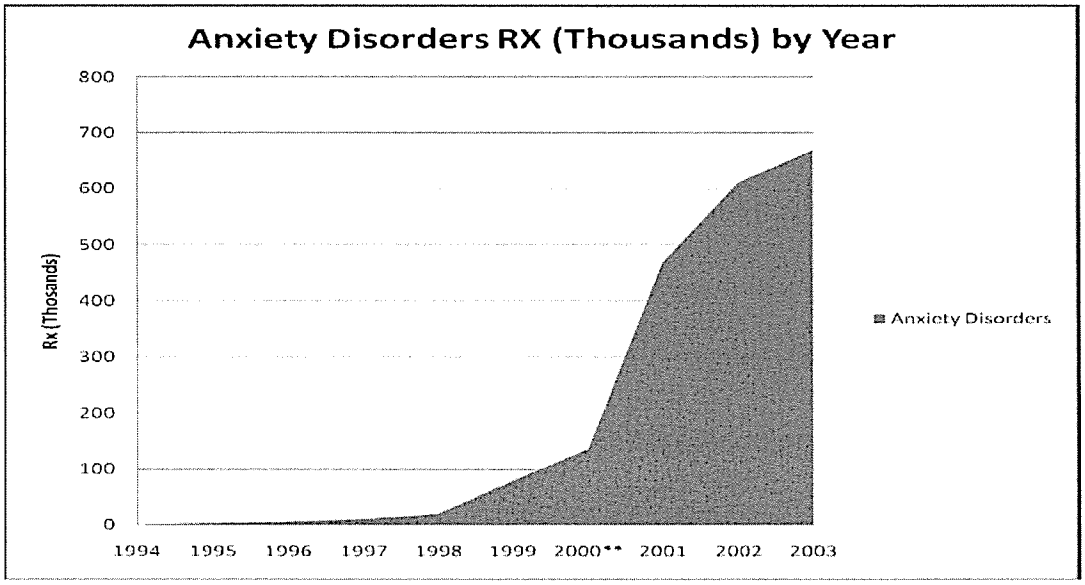
50. On May 19, 2003, a former medical liaison of Pfizer's subsidiary Warner Lambert, Dr. David Franklin, filed a lawsuit alleging that Pfizer's subsidiary had engaged in illegal sales and marketing practices with respect to Neurontin. Dr. Franklin submitted a sworn affidavit detailing the illegal off-label marketing strategy, including how medical liaisons were "trained and instructed to misrepresent the amount of clinical evidence available to support the use of Neurontin" and to "ignore and conceal any negative information about Neurontin." Warner Lambert's focus was on sales and profits, not on safety or legality. One Associate Director of Medical Affairs was quoted as instructing medical liaisons who visited doctors as follows:

> "Medical liaisons, this is Phil. I am calling in regard to the – you know, there's a Neurontin push that's supposed to be on. What we'd like to do is, anytime you're called out, just make sure that your main focus out of what you are doing is on Neurontin…. When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? And monotherapy and everything we can talk about, that's what we want to do."

51. Dr. Franklin further described that he was "trained and instructed to use a number of misleading abstracts and case reports" to promote Neurontin for "a variety of medically unacceptable uses." According to Dr. Franklin, Pfizer's subsidiary also trained medical liaisons

like himself to make offers of paid consultancy engagements, offers of paid participation in "studies," offers of junkets to first class resorts or hotels paid for by Warner Lambert, and offers of cash payments in order to induce physicians to prescribe Neurontin for off-label uses, and to prescribe it at higher doses than approved by the FDA.

52. Warner Lambert's illegal off-label promotion strategies were very successful and substantially increased the number of off-label Neurontin prescriptions. The following chart shows, for example, the increase in Neurontin off-label prescriptions for anxiety disorders from the start of defendants' off-label campaign in 1994 until 2003:[3]



53. Following the submission of Dr. Franklin's affidavit, the federal government opened an investigation. In 2004, Pfizer subsidiary Warner Lambert pled guilty to criminal and civil charges that it had fraudulently promoted the uses of Neurontin to treat a wide array of ailments for which the drug was not approved in violation of the FDCA. As the DOJ noted on May 15, 2004, Pfizer's subsidiary "***promoted Neurontin even when scientific studies had***

[3] Source: *In Re. Neurontin Marketing and Sale Practices Litig.*, MDL Docket No. 1629, Civ. Action No. 04-10981, Memorandum and Order (D. Mass. August 29, 2007).

shown it was not effective." The DOJ also noted that Warner Lampert's agents "made false or misleading statements to health care professionals regarding Neurontin's efficacy and whether it had been approved by the FDA for the off-label uses," that it used medical liaisons like Dr. Franklin "who represented themselves (often falsely) as scientific experts in a particular diseases, to promote off-label use for Neurontin," and that it "paid physicians to allow a sales representative to accompany the physician while he or she saw patients, with the representative offering advice regarding the patient's treatment which was biased towards the use of Neurontin." According to the DOJ, "[*t*]***hese tactics were part of a widespread, coordinated national effort*** to implement an off-label marketing plan."

54. To settle the charges, Pfizer's subsidiary pleaded guilty to two felony counts of violating the FDCA and Pfizer agreed to pay a $240 million criminal fine. The DOJ explained that this fine was "***the second largest criminal fine ever imposed in a health care fraud prosecution***." Pfizer agreed to pay an additional $190 million to resolve related claims under the civil False Claims Act, including allegations of violations of the Federal anti-kickback statute, that Warner Lambert's conduct had caused doctors to write prescriptions for Medicaid patients when those medications were not eligible for Medicaid reimbursement because those prescriptions were fraudulently obtained through false statements to doctors and by payment of illegal kickbacks, including so-called "consulting fees" and paid trips for doctors.

55. In addition to paying $430 million in civil and criminal fines, Pfizer entered into a "corporate integrity agreement" (the "2004 CIA") and agreed to comply with the terms of a corporate compliance program. The DOJ noted on May 15, 2004 that this agreement would ensure that "any future off-label marketing conduct is detected and corrected on a timely basis." In the preamble of the 2004 CIA, Pfizer represented that it had already initiated voluntary

compliance measures, including "the appointment of a Compliance Committee" and "regular mandatory training for all employees concerning Pfizer's Code of Conduct."

56. The 2004 CIA required that Pfizer maintain a disclosure program to enable employees to report violations of federal health care law and FDA regulations, and required the Compliance Officer to maintain a disclosure log to record a summary of each disclosure received, the status of any review and any corrective action taken in response. This disclosure program was required to "emphasize a nonretribution, nonretaliation policy" and to "include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained."

57. The 2004 CIA emphasized the important monitoring and oversight role of Defendants in ensuring that Pfizer would not again engage in illegal marketing and sales promotions of its drugs. It provided that Pfizer's Chief and Deputy Compliance Officers (both members of senior management) "shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time." The 2004 CIA noted that "[i]n these periodic reports, the Directors shall be notified of Pfizer's continuing activities and obligations under the [2004 Integrity Agreement]" and that "the Directors have agreed to abide by a Code of Conduct which they adopted."

58. Pfizer promised that this Code of Conduct or "Blue Book" would, among other things, set forth Pfizer's requirement that all of Pfizer's officers and employees were expected to comply with all Federal health care program requirements and FDA requirements. The 2004 CIA required, in this regard, that "all officers directly involved in Pfizer's US Pharmaceutical

operations" to certify that they "read, received, understood and shall abide by Pfizer's [code of conduct]," including the requirement that they would be "expected to comply with all Federal health care program requirements and FDA requirements."

59. Pfizer also agreed to implement written policies and procedures regarding the operation of Pfizer's compliance program and that those policies would, among other things, address (i) "the methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all FDA requirements;" (ii) policies designed to ensure that speaker meetings, advisory board meetings and all other consulting arrangements would be "used for legitimate purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products;" (iii) policies designed to ensure that Pfizer's sponsorship or funding of grants, research or related activities (including clinical trials, market research or authorship of other articles) comply with all applicable Federal health care program and FDA requirements; and (iv) "the methods for selling, marketing, and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute."

60. As set forth below, Pfizer's Board allowed violations of Federal law to continue unabated after Pfizer agreed to the terms and conditions of the 2004 CIA.

3. 2007 Criminal Fine and Settlement For Illegal Marketing of Genotropin

61. Genotropin is a human growth hormone (anabolic steroid) that was approved by the FDA for the limited use of treating children who suffer from growth failure because it can pose substantial risks to human health, particularly for teenagers. In the U.S., Genotropin is manufactured and sold by Pharmacia, a wholly-owned subsidiary of Pfizer. In the August 2004

edition of "Endocrine News," Dr. Linn Goldberg of the Hormone Foundations' Hormone Abuse Program Advisory Council noted for example that "[y]oung developing bodies are likely more sensitive to the ***adverse health effects of steroids, some of which can be irreversible*** such as stunting of height in males and voice and body/facial hair changes in females." The article further noted that a number of national studies had concluded that during 2001, when Pharmacia had already begun its efforts to illegally market the off-label use of Genotropin, "lifetime use of anabolic steroids was at a new high of 3.7 percent among 12th graders."

62. The FDCA also recognizes the substantial health risks posed by the use of human growth hormones like Genotropin for uses that are not approved by the FDA. Under the provisions of this statute, whoever knowingly distributes or possesses with intent to distribute human growth hormones for any use that is not approved by the FDA faces up to 5 years in prison, and up to 10 years in prison if the offense involves a minor. 21 U.S.C. §303.

63. Pharmacia did not seek approval from the FDA for use of Genotropin for athletic performance enhancement, anti-aging, or cosmetic use. Pharmacia also did not submit information to the FDA asserting that such other uses would be safe, and the FDA never approved such other uses. Knowing that it was illegal to do so, and with the intent to defraud and mislead, Pharmacia nevertheless marketed Genotropin for unapproved uses, including athletic performance enhancement, anti-aging, and cosmetic use.

64. The illegal off-label marketing and sales promotion of Genotropin was very successful – Pfizer's revenues from Genotropin increased from $481 million in 2003 to $843 million in 2007.[4]

65. In or about March 2007, Pharmacia entered into criminal guilty plea for the

[4] *See* Pfizer Form 10-K for 2003 *and* Pfizer Form 10-K for 2007 filed with the U.S. Securities and Exchange Commission.

illegal promotion and sales practices of Genotropin. Pfizer's subsidiary admitted that during visits to anti-aging doctors and clinics, "Pharmacia made misleading representations about the effectiveness of Genotropin as an anti-aging medication," that it "knew it was illegal to promote Genotropin for Unapproved Uses such as anti-aging," and that it had "earned millions of dollars in gross revenue from selling Genotropin for various Unapproved Uses." Moreover, Pfizer's subsidiary admitted that "[s]ome of the reasons that individuals took Genotropin had ***nothing to do with any medical condition***, but instead were to obtain better skin tone, better skin elasticity, better general appearance, and better ability to lift more weights at the gym."

66. In or about March 2007, Pharmacia also pleaded guilty to intentionally violating the Federal anti-kickback statute. Pharmacia admitted that it had knowingly and willfully offered excess payments on a contract with a drug distribution company to induce that company into recommending purchasing or ordering Pharmacia's pharmaceutical products that were eligible for payment under a Federal health care program.

67. To settle the charges regarding the illegal promotion and sales practices of Genotropin and the charges related to the Federal anti-kickback statute, Pfizer entered into a deferred prosecution agreement with the U.S. Attorneys' Office in Massachusetts. In addition, Pfizer agreed to pay $34.6 million in criminal fines.[5]

68. Nevertheless, the Pfizer Board again decided to take no meaningful action to prevent repetition of Pfizer's criminal conduct. Instead, the Board knowingly encouraged or consciously disregarded that behavior.

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[5] The criminal fine consisted of $15 million for the illegal promotion and sales practices of Genotropin and $19.6 million for intentional violations of the Federal anti-kickback statute.

C. The Defendants Breached Their Fiduciary Duties By Causing Pfizer to Incur the Largest Criminal Fine and Health Care Fraud Settlement In History

69. Despite these repeated violations, the continuing illegal conduct at the Company—involving some of the very practices at the center of the Lipitor. Neurontin and Genotropin settlements—ultimately subjected Pfizer to the largest government fines in history.

70. On September 2, 2009, Pfizer formally announced its agreement to pay a criminal fine of $1.195 billion and to forfeit $105 million to settle criminal charges related to the illegal, off-label marketing and promotion of Bextra, a non-steroidal anti-inflammatory drug ("NSAID") and competitor of VIOXX. As noted by the DOJ, this is "***the largest criminal fine ever imposed in the United States for any matter***."

71. Pfizer further agreed to pay an additional $1 billion to resolve allegations under the civil False Claims Act that between January 2001 and October 31, 2008 Pfizer engaged in the illegal promotion and sales practices of Aricept (cholinesterase inhibitor used for treating Alzheimer's decease), Celebrex (NSAID), Geodon (antipsychotic), Lipitor (cholesterol lowering drug), Lyrica (anti-epileptic), Norvasc (calcium channel blocker), Relpax ("5-HT1 agonist" used for treating migraines), Viagra (muscle relaxer), Zithromax (antibiotic), Zoloft (antidepressant), Zyrtec (antihistamine) and Zyvox (antibiotic).

72. According to the DOJ, this is "***the largest civil fraud settlement in history against a pharmaceutical company.***" The size and seriousness of the punishment of Pfizer reflected "the seriousness and scope of Pfizer's crimes."

73. Between January 2001 and October 31, 2008, the Board received many indications that Pfizer employees were violating FDA regulations, Federal healthcare program regulations or the Federal anti-kickback statute with regard to a number of these drugs. Those indications—or "red flags"—included various FDA warning letters and internal reports from

Pfizer employees discussed in more detail in ¶¶109-15, 134 below. However, the Board consciously ignored those red flags for more than seven years. Instead, Pfizer retaliated against a number of the employees who had made the reports of illegal behavior. This permitted and encouraged the lawbreaking employees to continue their illegal behavior, thereby placing the Company and its shareholders at risk.

1. The Illegal Off-Label Promotion of Bextra Subjects Pfizer To The Largest Criminal Fine In U.S. History

74. In or about January 2001, Pharmacia sought FDA approval for the sale of Bextra. Bextra is also known under its generic name "valdecoxib" and inhibits an enzyme that is responsible for transmitting inflammation and pain. The enzyme is called cyclooxygenase-2 and commonly referred to as "COX-2." Bextra is therefore frequently referred to as a "COX-2 inhibitor." Bextra's competed with VIOXX, another COX-2 inhibitor. Pharmacia specifically requested that the FDA approve use of Bextra for the treatment of "acute pain" and "dysmenorrheal" (severe uterine pain during menstruation) by administering 40 milligram ("mg") of Bextra/valdecoxib per day and, in addition, for the treatment of chronic symptoms of arthritis at a dose of 10 mg Bextra/valdecoxib per day, noting that some patients could benefit from an additional 10 mg per day. In its medical review of Bextra, the FDA summarized Pharmacia's "request for claims" as follows:

> An indication for the treatment of acute pain and dysmenorrhea at 40mg/d, with an additional 40mg on day one if needed, and an indication for chronic treatment of the signs and symptoms of osteoarthritis and rheumatoid arthritis at a dose of 10mg/day, with the proviso that "some may receive additional benefit at 20mg/day."

See FDA Center For Drug Evaluation And Research, Application No. 21-341, Medical Review,

p. 4 (Nov. 7, 2001) (hereinafter "FDA 2001 Medical Review").[6]

75. But the FDA denied Pharmacia's request, and rejected approval for Bextra to be used to treat "acute pain." The FDA largely based its rejection of Bextra's submission on safety concerns identified in a study of Bextra showing an increase of serious risks, including death, for certain patients who were given 40 mg of valdecoxib per day. Under the heading "Recommendations," the FDA 2001 Medical Review stated:

> ***Nonapproval of the acute pain, including opiod-sparing and prevention of operative pain***. The only substantial multidose safety database is found in the Coronary Artery Bypass Graft (CABG) Surgery study 035. ***This study demonstrated an excess of serious adverse events including death*** in association with the use of paracoxib and valdecoxib 40 mg bid when added to ad lib parenteral narcotic analgesia.

76. In addition, the FDA 2001 Medical Review concluded that the findings of this study warranted "further investigation before valdecoxib can be considered safe and effective for the treatment of pain, particularly multidose therapy in the perioperative setting," or before, during or after surgery.

77. According to the FDA 2001 Medical Review, these serious adverse events were associated with an increased risk of the formation of clots in blood vessels that could break loose and be carried by the blood stream to plug another vessel. If carried to the lungs, blood clots can lead to a potentially lethal pulmonary embolism. If carried to the brain, blood clots can lead to a potentially lethal stroke; if carried to the heart, blood clots can result in a potentially lethal heart attack. Because the individuals who received Bextra in the study were also given aspirin to thin their blood in order to prevent such serious adverse effects, this higher risk of the formation of blood clots was of particular concern to the FDA medical reviewer. As explained in the FDA

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[6] *Available at* http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_24_Y-FDA-Tab-O.doc (last viewed on September 13, 2009).

2001 Medical Review:

> The excess of serious cardiovascular thromboembolic events….is of note as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events. Given the emerging concern over a possible pro-thrombotic action of certain agents in the COX2 class, ***these data are of concern***.

78. Ultimately, the FDA only approved Bextra "for the indications of osteoarthritis and rheumatoid arthritis at a dose of 10mg/day and dysmenorrhea at a dose of 20-mg bid as needed."

79. The FDA shared the results of the its 2001 Medical Review – including the FDA's denial of approving use of Bextra for acute pain or for perioperative setting and the noted risks and concerns of Bextra dosages higher than 20 mg per day – with Pharmacia. The FDA medical reviewer expressly noted that he had "***emphasized the importance of rigorously testing the overall safety … of valdecoxib***" in discussions with the Company. The Company, therefore, knew that the off-label prescription of Bextra for higher dosages than 20 mg per day, or for other uses than the FDA had approved, would be dangerous to human health and life.

80. Despite the FDA's denials and concerns, Pharmacia immediately started to draw up plans to market Bextra to a broad range of patients. On or about March 12, 2002, Heidi Chen and Debbie Walters of Pharmacia's legal division gave a presentation about the market for COX-2 inhibitors, including a possible "Pfizer/Pharmacia alliance," "COX-2 Portfolio Positioning" and "special COX-2 Challenges." Under the heading "COX-2 Franchise," the presentation stated that the first COX-2 inhibitor launched in the U.S. – Pfizer drug Celebrex – had achieved $3.1 billion in global sales in 2001 and had already been taken by more than 20 million patients. Directly underneath the description of Celebrex, Pharmacia placed a description of Bextra, announcing that it would be the third COX-2 inhibitor launched in the U.S. and was "filed in 25

countries." Elsewhere the presentation stated that, in 2001, the size of the "Arthritis and Pain Market" was $9 billion in sales and that Bextra was projected to generate $1 billion in sales by 2004 "or sooner!!"

81. Despite the FDA's express denial of approval for use of Bextra to treat acute pain in November 2001, the March 2002 presentation stated that Bextra would "pursue" acute pain and that the market "positioning message" of Bextra would be: "Meet All Arthritic & Pain Relief Needs."

82. In or about 2002, Pharmacia entered into an alliance with Pfizer to market Bextra together with Pfizer's COX-2 inhibitor Celebrex. Pfizer acquired Pharmacia a year later. As part of the marketing alliance, Pfizer and Pharmacia shared information about sale and promotion strategies for both Bextra and Celebrex.

83. On or about October 4, 2002, South Florida district manager Matthew Lustig sent an email to numerous Pfizer medical sales representatives and Pfizer Senior District Sales Manager Michael Milano attaching an article from research journal "The Lancet." The article was entitled "COX-2 selective non-steroidal anti-inflammatory drugs and risk of serious coronary heart disease." According to the study, patients taking high doses of Merck's VIOXX were 1.7 times more likely to suffer serious coronary heart disease than patients who did not use any medication and 1.78 times more likely than an patient's taking Pfizer's Celebrex. Like VIOXX and Celebrex, Bextra was a COX-2 inhibitor. Lustig's email to Pfizer's medical sales representatives therefore stated that "every representative should know of its contents" and that "[s]ince negative information on any COX II sometimes hurts all COX II's it should be mentioned or discussed only after careful consideration of the impact it may have with that specific doctor."

84. On or about October 28, 2002, Pfizer's Michael J. Langan sent an email to two colleagues discussing the results of a meeting "with the Anesthesia Department the other day to discuss that role of COX II's in the Multi Modal Approach to Pain Surgical Management." Although the FDA had expressly warned that further investigation was warranted before Bextra "can be considered safe and effective for the treatment of pain, particularly multidose therapy in the perioperative setting," Langan stated that "Doctors can reduce the use of narcotics by using Bextra/Celebrex. As part of the Pain Management."

85. The joint Pharmacia/Pfizer strategy of off-label marketing and promotion of Bextra for acute pain and use in the perioperative setting continued after Pfizer acquired Pharmacia in 2003.[7] During this time, Pfizer and Pharmacia continued to position Bextra as a competitor for VIOXX – which was used by physicians to treat acute pain – while avoiding cannibalizing the sales and market share of Pfizer's other COX-2 inhibitor, Celebrex, which was often used for chronic conditions.[8] Between late 2001 and late 2003, Pharmacia also held almost 100 consultant meetings to promote unapproved uses and dosages of Bextra and in the process entertained over 5,000 health care professions. During many of these meetings, Pharmacia paid physicians to further spread its message about unapproved uses and dosages of Bextra.[9]

86. Moreover, Pfizer's subsidiary also: (i) illegally promoted Bextra with false and misleading safety and comparative claims; (ii) created sham doctor requests for medical information about unapproved uses in order to send unsolicited information about unapproved uses and dosages of Bextra; (iii) distributed promotional samples with unapproved dosages to surgeons and other doctors who had no FDA-approved use for those samples; (iv) funded

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7 *See* Criminal Complaint in *U.S. v. Pharmacia*, ¶¶23-32, 39-51.
8 *Id.* at ¶24.
9 *Id.* at ¶¶37, 38.

purportedly independent continuing medical education programs to promote Bextra for unapproved uses, including acute pain and surgical pain; and (v) employed a publication strategy by funding, sponsoring and sometimes drafting articles about Bextra for unapproved uses and dosages in order to promote such unapproved uses and dosages.[10]

87. In or about September 2004, Merck announced that it would remove VIOXX from the market. This removal was based on a clinical trial that had shown an increased risk of serious "thrombotic events" including heart attack and stroke in certain patients following the use of VIOXX for more than 18 months. Based on the withdrawal, the European Medicines Agency ("EMEA") announced on October 6, 2004 that it would "review available long term data on cardiovascular safety for all licensed COX-2 inhibitors" including Bextra, within two weeks.[11] In October 2004, Pfizer also learned the results of a second study of Bextra in coronary artery bypass graft surgery (the "Second CABG study"). This study showed a statistically significant increase in thrombembolic cardiovascular events in patients taking Bextra following the administration of another Pfizer drug called parecoxib.[12]

88. Following the 2001 FDA Medical Review, Pfizer was thus again placed on notice by the October 2004 announcement of the EMEA and by the results of the Second CABG study that Bextra could pose serious health risks for patients, even if solely prescribed for FDA approved use and dosage. Pfizer nevertheless continued its illegal practice of promoting Bextra "off-label" for uses and dosages other than the uses and dosages approved by the FDA.[13]

89. On January 10, 2005, the FDA sent a letter informing Pfizer that certain Pfizer

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10 *See id.* at ¶¶55-75.

11 *See* Doc. Ref. EMEA/97949/2004

12 *See* Criminal Complaint in *U.S. v. Pharmacia*, ¶20.

13 *Id.* at ¶22 (noting that "From in or about February 2002 ***through April 2005***, Pharmacia promoted the sale of Bextra, as set forth below, for uses and dosages other than the Approved Uses and Dosages and/or with false and misleading claims of safety and efficacy and without disclosing the FDA's safety concerns." (emphasis added.)

promotional materials contained misleading safety claims regarding Bextra, including safety claims that were "inconsistent with the Warning in the Bextra [FDA approved labeling] regarding serious and life-threatening … side effects, including bleeding in the stomach and intestines." The FDA letter also stated that a 27 minute Pfizer TV infomercial for Bextra was "misleading because it overstates its proven effectiveness and omits important information about the drugs' safety and effectiveness." Pursuant to the terms of the 2004 Corporate Integrity Agreement, the Compliance Officer and the Deputy Compliance Officer were obligated to inform the Pfizer Board of this FDA letter. Despite the letter, Pfizer continued its illegal practice of promoting Bextra "off-label" for uses and dosages that were not approved by the FDA.

90. On January 18, 2005, the EMEA's Committee for Medicinal Products for Human Use held a hearing with Pfizer and other pharmaceutical companies about the safety of COX-2 inhibitors. The outcome of the EMEA review of the safety of COX-2 inhibitors would impact Pfizer's ability to sell Celebrex and Bextra in Europe and was of exceptional importance to Pfizer. Upon information and belief because of the financial importance to Pfizer, the Pfizer Board was informed of this hearing and the safety concerns underlying the EMEA's review.

91. On February 17, 2005, the EMEA issued a public statement announcing regulatory action on all COX-2 inhibitors and stating that the EMEA's Committee for Medicinal Products for Human Use had concluded that "the available data show an increased risk of cardiovascular events for COX-2 inhibitors as a class."[14] The EMEA therefore announced a series of "interim measures" and recommended that "[g]iven the association between cardiovascular risk and exposure to COX-2 inhibitors, ***doctors are advised to use the lowest effective dose for the shortest possible duration of treatment***." Upon information and belief

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[14] *See* Doc. Ref. EMEA/62838/2004

because of the financial importance to Pfizer, the Pfizer Board was informed of the EMEA's regulatory action. Despite the EMEA's findings and express recommendation to use the lowest effective dose for the shortest possible duration of treatment, Pfizer continued its illegal practice in the U.S. of promoting Bextra "off-label" for uses and dosages other than the uses and dosages approved by the FDA.[15]

92. On or about April 7, 2005, the FDA requested that Pfizer voluntarily withdraw Bextra from the U.S. market. The FDA explained that Bextra had been "been demonstrated to be associated with an increased risk of serious adverse [cardiovascular] events in two short-term trials." Pfizer agreed to do so, and ceased all sales and promotion activities in the U.S., including the illegal promotion of off-label use for Bextra.

93. On or about June 2009, one of Pfizer's regional sales managers, Mary Holloway, was sentenced for her role in the off-label promotion of Bextra by the Federal District Court in Massachusetts to a fine and two years of probation. But Holloway was not acting on her own, in isolation or without the knowledge of her superiors at the Pfizer. Rather, Pfizer's off-label promotion of Bextra was widespread within the Company, approved of by the Company, and generally part of the Pfizer culture. As Ms. Holloway's sentencing memorandum submitted to the Court stated:

> Ms. Holloway's region dutifully reported Bextra protocols attained for orthopedic, podiatry, urology, ob/gyn, ENT and dental indications, where much of the usage was off-label. ***Corporate tracked this information, and at no time did it inform Ms. Holloway that any of the reported protocols were inappropriate***.

See Mary Holloway's Sentencing Memorandum to the Federal District Court of Massachusetts, Case Number 09-cr-10089-JGD, dated June 12, 2009.

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[15] *See* Criminal Complaint in *U.S. v. Pharmacia*, ¶22.

94. On or about August 2009, Pfizer's subsidiary Pharmacia agreed to plead guilty to a criminal felony charge of violating the FDCA, admitting that it intentionally, and with the intent to deceive and defraud, marketed Bextra for uses and dosages that were not approved by the FDA. The deceptive sales conduct regarding Bextra took place from February 2002 through April 2005. During this time, Pfizer knew that Bextra was dangerous to human life. As noted by the U.S. DOJ on September 2, 2009, "***Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns***."

95. To settle the criminal charges, Pfizer agreed to pay a fine of $1.195 billion, which, according to the DOJ, is "the largest criminal fine ever imposed in the United States for any matter." The calculation of the fine was set forth in an August 31, 2009 letter from the prosecuting attorney to Pfizer's counsel. The letter documented the agreement with Pfizer's subsidiary that it agreed to a $1.3 billion fine in part because:

> "the organization had 5,000 or more employees, and an individual within the high level personnel of the unit participated in or condoned the offense and/or ***tolerance of the offense by substantial authority personnel was pervasive throughout the organization***."

96. According to the government's prosecuting attorney, the size of the punishment of Pfizer reflected "the seriousness and scope of Pfizer's crimes." The government's prosecuting attorney added that "Pfizer violated the law over an extensive time period" and that "at the same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

2. The U.S. Government Imposes A $1 billion Settlement on Pfizer – The Largest Civil Fraud Settlement Ever Paid By A U.S. Pharmaceutical Company

97. In addition to paying $1.3 billion in criminal fines regarding the illegal promotion and sales practices of Bextra, Pfizer also agreed to settle allegations that it had violated the Federal civil claims act, including prohibited off-label use and dosage promotions, and violations of the Federal anti-kickback statute, with respect to 13 different drugs.

98. Pfizer's illegal conduct, which spanned over seven years, between January 1, 2001 and October 31, 2008, involved Company-wide marketing practices and some of Pfizer's most material and important products. Of Pfizer's nine most important pharmaceutical products—those generating over a $1 billion per year in revenue each (representing 60 percent of the Company's total pharmaceutical revenues in 2008) and which Pfizer admits in its SEC filings could have a "significant" impact on the Company's revenues should they "become subject to problems such as…regulatory proceedings"—*seven* (Lipitor, Norvasc, Lyrica, Celebrex, Viagra, Geodon and Zyvox) were included in the $2.3 billion settlement as drugs that were promoted for off-label uses and/or through illegal kickbacks and other improper means. These violations are plainly not isolated incidents, or the work of a small number of "rogue" employees. Rather, the $1 billion payment to settle those charges was the culmination of a deliberate general business strategy to illegally promote off-label use, including by making false or unsubstantiated claims regarding the efficacy and safety of Pfizer drugs and payment of illegal remuneration to doctors to induce them to prescribe Pfizer drugs.

99. The settlement agreement, which identifies four major Pfizer pharmaceuticals that were extensively promoted for off-label uses, summarizes some of this misconduct as follows:

(1) **Bextra:** During the period February 1, 2002, through April 30, 2005, Pfizer:

(a) illegally promoted the sale and use of Bextra for a variety of conditions (including acute pain and various types of surgical pain) and at dosages other than those for which its use was approved by the Food and Drug Administration ("FDA") (*i.e.*, "off-label" uses), in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Bextra;

(b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Bextra, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and

(c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Bextra. As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Bextra to be submitted to, or caused purchases by, Medicaid and the other Federal Health Care Programs.

(2) **Geodon:** During the period from January 1, 2001, through December 31, 2007, Pfizer:

(a) illegally promoted the sale and use of Geodon for a variety of off-label conditions (including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism and post-traumatic stress disorder), and for patients (including pediatric and adolescent patients) and dosages that were off-label, in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Geodon;

(b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Geodon, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and

(c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Geodon. As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Geodon to be submitted to,

or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

(3) **Zyvox:** During the period January 1, 2001, through February 28, 2008, Pfizer:

(a) illegally promoted the sale and use of Zyvox for a variety of off-label conditions (including infections caused by methicillin-resistant *Staphylococcus aureus* ("MRSA") generally, rather than only those types of MRSA infections for which Zyvox was FDA-approved), in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Zyvox;

(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zyvox (including that Zyvox was superior to vancomycin, its primary competitor drug for these indications); and

(c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zyvox, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Zyvox to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

(4) **Lyrica:** During the period September 1, 2005, through October 31, 2008, Pfizer:

(a) illegally promoted the sale and use of Lyrica for a variety of off-label conditions (including chronic pain, neuropathic pain, perioperative pain, and migraine), in violation of the FDCA, 21 U.S.C. § 331, et seq., and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Lyrica;

(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Lyrica, including claims that it was superior to Neurontin and its generic equivalent, gabapentin; and

(c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Lyrica, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or

fraudulent claims for Lyrica to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

(5) **Kickbacks:** From January 2001, through December 2004, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs, and gifts (including entertainment, cash, travel and meals) to health care professionals to induce them to promote and prescribe the drugs Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, Pfizer caused false claims to be submitted to Medicaid and TRICARE.

100. As a result of the settlement, Pfizer entered into yet another corporate integrity agreement that supersedes the 2004 CIA and includes additional, enhanced compliance requirements (the "2009 CIA"). Indicating failures of Pfizer's Board to carry out its duties under the 2004 CIA to prevent the illegal off-label and other improper marketing activities that led to the $2.3 billion settlement, the 2009 CIA imposes new obligations on the Board's Audit Committee, requiring the Committee to meet quarterly to review and oversee the Company's compliance activities and evaluate their effectiveness. Further, upon each quarterly review, the Audit Committee must adopt a resolution summarizing its inquiry into and oversight of Pfizer's compliance with federal health program requirements, FDA regulations and the Company's obligations under the CIA. The resolution—which must be signed by each individual member of the Committee—must verify that Pfizer's compliance program has been effective to "meet Federal health care program requirements, FDA requirements, and the obligations of the CIA." If a Committee member is unable to do provide such an affirmation, the Audit Committee must include a written explanation of the reasons "why it is unable to provide the conclusion and the steps it is taking to assure implementation by Pfizer of an effective Compliance Program at Pfizer."

101. The 2009 CIA also mandates similar compliance measures for management,

requiring that the presidents and finance directors of each business unit involved in pharmaceutical sales complete a certification affirming that they have taken appropriate steps to ensure compliance, that the relevant business unit's leadership team has not directly or indirectly encouraged policy violation, and that controls are operating effectively. Similar to the verifications required of the Audit Committee members, the management certifications must also affirm that the certifying individual has reviewed 1) internal reports addressing promotional quality assessments; 2) reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses; 3) sales compensation exclusion criteria; and 4) corporate compliance group statistics. In addition, the certifying executive must verify that no violation of law, regulation, Pfizer policy or the CIA has occurred, or if an issue has been identified, affirm that the potential violations have been referred to the Corporate Compliance Group or a member of the Pfizer legal division.

102. Moreover, the new 2009 CIA requires the Board to review compliance measures on a more frequent basis, requiring that the Chief Compliance Officer submit reports to the Board's Audit Committee on at least a quarterly basis. Further, the Chief Compliance Officer—who must not be the same individual who acts as general counsel for the Company—cannot be subordinate to the General Counsel or the Chief Executive Officer, but must be a member of senior management who reports directly to the Chief Executive Officer. This significant change will require that Defendant Associate General Counsel Douglas M. Lankler, who currently serves as Pfizer's Chief Compliance Officer, be replaced, and represents a significant departure from the practice under the 2004 CIA, where Defendant Kindler acted as both Pfizer's General Counsel and its Chief Compliance Officer.

3. Pfizer Admits Systemic, Company-wide Abuses to Resolve the Civil and Criminal Allegations

103. In order to resolve the serious legal violations and charges sought by the DOJ and avoid potentially ruinous criminal convictions, fines and/or debarment, Pfizer not only paid the largest government fine ever, but also made significant admissions evincing a shocking disregard for the health and safety of the millions of patients who took its drugs. Indeed, the Company's culpability for the crimes and other violations alleged by the DOJ cannot be seriously disputed.

104. Although Pfizer's wholly-owned subsidiary, Pharmacia, which was acquired by Pfizer in 2003, is the actual party entering a guilty plea to resolve criminal charges related to Pfizer's illegal off-label promotion of Bextra, the DOJ settlement requires the parent Company to acknowledge responsibility for the misconduct, which, according to the criminal information, continued under its watch until at least 2005. Moreover, pursuant to a side letter agreement that the DOJ entered into with Pfizer as part of the resolution of the criminal matter against Pharmacia, "Pfizer acknowledges that Pharmacia & Upjohn Company, Inc. expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the information and is in fact guilty of that offense." Under the Company's agreement with the DOJ, Pfizer is prevented from making any public statements "inconsistent with this explicit admission of guilt by Pharmacia & Upjohn Company to the crime charged in the Information."

105. In addition to admitting allegations of the Company's unlawful promotion of Bextra, described above in paragraphs ¶¶74-94, Pfizer also admitted specific facts regarding its illegal marketing of Zyvox—an antibacterial agent that is approved by the FDA to treat certain types of infections, including nosocmial pneumonia caused by methicillin-resistant staphylococcus aureus ("MRSA")—that underscore the cavalier attitude the Company took in

complying with its legal obligations and those imposed by the 2004 CIA.

106. Specifically, Pfizer admitted that it continued to illegally misbrand Zyvox even after the FDA issued a Warning Letter to Pfizer's Chairman and CEO on July 20, 2005 expressly warning Pfizer that such conduct violated federal law. After initially receiving the letter, Pfizer agreed, at the FDA's request, to publish a corrective advertisement noting the FDA's objection to Pfizer's earlier superiority claims and to take steps to ensure that the advertisement and similarly objectionable promotional would not be used by sales representatives.

107. But, as Pfizer admitted in papers filed in the settlement, the Company—with the encouragement of headquarters-based executives—continued to promote Zyvox through the very unsubstantiated claims that the FDA identified as false, misleading and unlawful. In particular, Pfizer admitted that, even after its Chairman and CEO received the FDA warning letter:

> ...Pfizer's sales representatives thereafter continued to make claims to physicians that Zyvox was superior to [competitor drug] vancomycin for certain patients with MSRA, which included the claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with the FDA's Warning Letter and Zyvox's FDA approved label, and which were inconsistent with the manner in which Pfizer, after receipt of the Warning Letter, agreed to present the clinical data cited by the FDA.
>
> Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.

108. These admitted facts—and the numerous similar allegations contained in nearly a dozen whistleblower *qui tam* lawsuits confirming Pfizer's misconduct and the illicit nature of its corporate business strategy throughout the Relevant Period—further support Defendants' culpability in approving of and/or failing to prevent these widespread abuses.

D. The Director-Defendants Did Not In Good Faith Discharge Their Duties To The Company, Causing Pfizer's Obligation To Pay The Largest Criminal And Civil Health Care Fraud Settlement In History

109. The illegal sales and promotion practices covered by the 2009 settlement spanned more than 7 and a half years and 13 different drugs. During this time, the Pfizer Directors were repeatedly informed of allegations that Pfizer employees were engaged in illegal sales and promotion practices, including promotion of off-label uses and dosages, the dissemination of false and misleading information to induce doctors into prescribing Pfizer drugs, and offers of remuneration to doctors who did prescribe Pfizer drugs. Defendants also knew that, if true, such alleged practices put at risk the health and lives of patients.

110. Indeed, Defendant Kindler, who, in his role as General Counsel for Pfizer from 2002 through 2006, served as the Company's Chief Compliance Officer, was specifically charged under the Corporate Integrity Agreements as the individual at the Company "responsible for developing and implementing policies, procedures, and practices designed to ensure compliance" with the federal health care laws, FDA regulation and the CIAs and for "monitoring the day-to-day compliance activities engaged in by Pfizer as well as for any reporting obligations created" under the CIA.

111. As noted above, the 2002 and 2004 Corporate Integrity Agreements emphasized the important monitoring and oversight role of the Directors in ensuring that Pfizer would not engage in illegal marketing and sales promotions of its drugs. The 2004 CIA noted that "the Directors have agreed to abide by a Code of Conduct which they adopted." Under the terms of the 2004 CIA, Pfizer's Compliance Officer and Deputy Compliance Officer were authorized to report on Pfizer's compliance with all applicable FDA requirements, Federal healthcare program requirements and the Federal anti-kickback statute "***directly to the Board of Directors of Pfizer***" or its designated subcommittee "at any time," ***and they were required to do so at least semi-***

annually. In addition, Pfizer's Compliance Officer and Deputy Compliance Officer were required to inform the Directors about reports from employees under the disclosure program that Pfizer employees were violating federal law, as well as FDA notice of violation letters warning of the very same misconduct violating federal law that were part of the $2.3 billion settlement.

112. During the Relevant Period, Pfizer's Chief and Deputy Compliance Officers repeatedly informed the Pfizer Board of allegations that Pfizer employees were engaged in illegal sales and promotion practices. Among other red flags, the Board was informed of:

- ***September 3, 2002 FDA violation notice regarding Geodon*** informing Pfizer that it was engaged in the promotion of Geodon "in a manner that is misleading and lacking fair balance because it minimizes important risk information regarding the greater capacity of Geodon to cause QT prolongation, and the potential to cause torsade de pointes-type arrhythmia and sudden death." The FDA therefore requested that Pfizer "immediately discontinue the use of these and any other promotional materials and activities with the same or similar issues" and "to respond to this letter within ten days," including "a list of all promotional materials with the same or similar issues."

- ***2003 anti-kickback statute violation reports regarding Lipitor, Viagra, Zyrtec, Norvasc, Zithromax, Zoloft, Glucotrol*** by Pfizer employee Blair Collins to compliance personnel. Collins alleged that he was improperly forced to resign in retaliation for making these reports, and he commenced a *qui tam* action in 2004.

- ***2004 Neurontin Settlement***, including (i) the facts and circumstances leading to the second largest criminal fine that was ever imposed in a health care fraud prosecution before 2004, such as illegal promotion of off-label uses, dissemination of misleading information to doctors, and improper offers of remuneration to doctors to induce prescription of a Pfizer drug; and (2) the 2004 CIA, including the obligations of Pfizer employees, officers and directors.

- ***2003-2004 misleading promotion reports regarding Geodon, Bextra, Celebrex, Relpax, and Lyrica*** by Pfizer employee Glenn Demott to Pfizer's national compliance office in New York about the illegal use of unreliable and flawed studies to improperly promote the drugs' efficacy. Demott alleged that he was improperly forced to resign in retaliation to making these reports, and he commenced a *qui tam* action in 2005.

- ***January 10, 2005 FDA violation notice regarding Bextra and Celebrex*** informing Pfizer that the FDA had reviewed five promotional pieces and that those materials variously "omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-

approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." The FDA noted that Bextra and Celebrex were "associated with a number of serious risks" and requested that Pfizer immediately cease the dissemination of violative promotional materials. The FDA further noted that "[t]he seriousness of the violations concerning your promotion of Celebrex described above would generally have warranted a Warning Letter; however, in light of your recent agreement to voluntary suspension on all consumer promotion for Celebrex, we do not feel that is appropriate at this time. You should be aware, however, of the serious nature of the violations described above and act to avoid disseminating similarly misleading promotion materials for your products in the future."

- ***July 20, 2005 FDA WARNING LETTER*** directly sent to the attention of Pfizer's Chief Executive Officer to inform Pfizer of serious violations of the FDCA and FDA implementation regulations regarding advertising for ZYVOX by: (i) improperly claiming that ZYVOX was superior to another drug without medical evidence supporting the claim; (ii) improperly suggesting off-label use of ZYVOX by claiming, without substantial evidence or substantial clinical experience, that ZYVOX could be used to treat a broader range of infections than the use approved by the FDA; and (iii) failing to reveal important risk information that may result from the use of ZYVOX.

- ***2006 off-label promotion reports regarding Lyrica*** by Pfizer professional health care representative Robert Liter to Pfizer compliance personnel, to Pfizer's corporate counsel Lisa Shrayer, and to Pfizer's outside counsel from Davis Polk & Wardell LLP about the illegal off-label promotion of Lyrica, including by producing unsolicited "medical inquiries"—requests from doctors for information about a drug that are intended to help doctors determine whether or not a drug will be effective.

- ***2006 and 2007 off-label promotion reports regarding improper marketing of Lyrica***—including through use of unsubstantiated and misleading claims, such as the sales representatives' use of "Pfizer math" to create the false impression that certain studies showed the drug's superiority over a competitor product—by Pfizer sales representatives David Farber and Casey Schildhauer who reported these improper and illegal marketing activities to Pfizer management. Farber and Schildhauer alleged that they were improperly forced to resign or terminated in retaliation to making these reports and commenced a *qui tam* action in 2007.

- ***2006-2007 off-label promotion reports regarding Geodon*** by Pfizer sales representative Mark Westlock to compliance personnel, human resources, Pfizer district manager Cheryl Shaughnessy, Pfizer regional manager Curt McAllister, Pfizer vice-president Amy Pitts, and Pfizer president of U.S. pharmaceutical operations, Defendant Ian Read, regarding Pfizer's illegal practice of promoting Geodon for the dangerous off-label use of treating agitated dementia in the elderly. Westlock alleged that he was improperly forced to resign in retaliation for making these reports, and he commenced a *qui tam* action in 2008.

- ***2007 Genotropin settlement and deferred prosecution agreement*** of criminal charges regarding the promotion of off-label use of Pfizer's human growth hormone (steroids) Genotropin for athletic performance enhancement, anti-aging, or cosmetic use, and charges related to the Federal anti-kickback statute.

- ***July 16, 2007 FDA violation notice regarding Geodon*** informing Pfizer that the FDA had reviewed a professional journal advertisement for Geodon that was "false or misleading because it omits important risk information and contains unsubstantiated superiority claims." The FDA stated that although the ad discussed some risk information the "journal ad fail[ed] to communicate other serious warnings and precautions associated with Gedeon…." The FDA further stated that the ad was misleading because it implied that Gedeon was more effective than a competitor in a particular use "when this has not been demonstrated by substantial evidence or substantial clinical experience." The FDA requested that Pfizer "immediately cease dissemination of violative promotional materials for Gedeon…."

- ***2008 qui tam lawsuit regarding allegations of off-label promotion of Zyvox***, filed by Pfizer District Manager Ronald Rainero and detailing allegations of improper off-label promotion, including management's encouragement of sales representatives to use misleading and unsubstantiated claims to promote the drug.

- ***April 16, 2008 FDA WARNING LETTER*** directly sent to the attention of Pfizer's Chief Executive Officer, Defendant Kindler, to inform Pfizer of serious violations of the FDCA regarding advertising for VIAGRA because Pfizer's promotional material "raises public health and safety concerns through its complete omission of risk information for Viagra by suggesting that Viagra is safer than has been demonstrated." The FDA further stated that "Viagra is associated with headaches, flushing, dyspepsia and abnormal vision" and asked Pfizer to "immediately cease dissemination of violative promotional materials for Viagra that are the same as or similar to those described above."

113. Many of the red flags reported to the Pfizer Board involve similar illegal conduct by different Pfizer employees. This raised an additional red flag as to whether the illegal sales and marketing practices were condoned – if not encouraged – by senior management.

114. The Directors knew that, if true, the red flags put at risk the viability of Pfizer's business, and that they had a duty to investigate and stop those practices from continuing. Each of them had undertaken a duty to oversee the company's compliance with federal law and regulations through the Company's Director Code of Conduct. This was especially true of the Defendants who were members of the Corporate Governance and Audit Committees, because

those were expressly created to monitor the Company's business and compliance process. The Charter of the Audit Committee provides that members of the committee must monitor the Company's compliance with laws, regulations, and internal procedures, including compliance with healthcare program regulations, FDA requirements and the 2004 CIA. The Charter of the Corporate Governance Committee provides that members of the committee must stay informed regarding matters of Pfizers' corporate governance and to "monitor emerging issues potentially affecting the reputation of the pharmaceutical industry and the Company."

115. The Defendants consciously disregarded their duties and, as evidenced in the very large criminal and civil fines, chose not to properly investigate and end the illegal sales and promotion practices that were taking place. In the meantime, Pfizer retaliated against a number of the employees who had made the reports of illegal behavior. Defendants' deliberate inaction and Pfizer's retaliation against employees who reported illegal sales and promotion practices – despite the obligation in the 2004 CIA that the disclosure program include a nonretaliation policy – encouraged lawbreaking employees to continue their illegal behavior. Defendants' deliberate inaction also created a culture of tolerating, if not rewarding and encouraging, unlawful conduct. Defendants' conscious breach of duty thereby placed the Company and its shareholders at risk.

E. A Future Criminal Conviction For Illegal Marketing Practices Could Make Pfizer Ineligible for Medicaid and Medicare And Lead To Ruinous Consequences For The Company And Its Shareholders

116. The Board's decision to allow a large part of Pfizer's business to be run as a *de facto* criminal enterprise has put (and if not stopped will continue to put) Pfizer and its shareholders at risk. On September 4, 2009, a *Bloomberg* article entitled "AIG of Drugmakers Pfizer Is Too Big to Be Guilty" noted that "Pfizer is fortunate to avoid criminal prosecution" and that "[g]iven the scope of the alleged misconduct, potential harm to the public, mistreatment of employees who insisted on following the law and its history as a repeat offender (excuse me,

make that a repeat-settler), it got off lightly." According to the article, "if Pfizer were convicted of a crime, it would face debarment from federal programs" resulting in ruinous consequences for Medicaid and Medicare patients who "would have to either somehow pay pocket for vital medicines the company produces or go without." As many millions of patients would not be able to afford Pfizer products, federal debarment would therefore also lead to ruinous consequences for Pfizer and its shareholders.

117. Indeed, there is good reason to believe that Pfizer is continuing on its path of widespread illegal marketing practices. Just two months after the Company informally agreed to the $2.3 billion settlement in January 2009, Pfizer received a letter from the FDA informing Pfizer that it was violating Federal law by misbranding various drugs on the Internet by failing to provide any risk information. This even included one of the drugs covered by the $2.3 billion settlement, Lyrica. The FDA stated that "the sponsored links misleadingly suggest that Aromasin, Caduet, Chantix, Detrol LA, Lyrica, and Celebrex are safer than has been demonstrated," and demanded that Pfizer cease this illegal activity "immediately."

V. PFIZER'S FALSE AND MISLEADING PROXY STATEMENTS

118. Pfizer's Proxy Statements for the years of 2007-2009 contained materially false and misleading statements and omissions because they failed to disclose that the Company's impressive financial results were only made possible through a criminal Company-wide effort to illegally market Pfizer drugs—including seven of Pfizer's nine most important pharmaceutical products responsible for over a $1 billion in revenue per year each—that exposed the Company and its shareholders to tremendous regulatory, reputational and financial risk. The Company's apparent financial success was one of the reasons Pfizer's shareholders reelected each of Pfizer's incumbent directors at Pfizer's annual meetings in 2007, 2008 and 2009, even though these Board actions violated Pfizer's own criteria for Board membership, and caused Pfizer's

shareholders to approve in 2009 a new plan of stock grants to employees based on Company performance. Approval for these measures would not have been granted had the true facts been disclosed to shareholders.

119. For example, Pfizer's 2007 Proxy Statement, filed on March 15, 2007 addressed the role and responsibilities of Pfizer's board of directors without disclosing their decision not to act on Pfizer's widespread violations of federal law. The 2007 Proxy Statement addressed the Board's role as the "ultimate decision-making body," (*id.* at 6), which manages the "business, property and affairs," of Pfizer, Inc., (*id.* at 15). Similarly, the 2007 Proxy Statement describes the Board of Directors' Audit Committee's responsibilities as including "the oversight of . . . the Company's compliance with legal and regulatory requirements." (*Id.*, Annex 2 at iii). In particular, the 2007 Proxy Statement provides that the Audit Committee "shall review (a) the status of compliance with laws, regulations and internal procedures." (*Id.*, Annex 2 at v; *accord id.* at 16 ("The Committee reviews reports from management relating to the status of compliance with laws, regulations and internal procedures.")) In addition, the 2007 Proxy Statement provides that the Board's Corporate Governance Committee shall monitor corporate governance matters generally, and in particular "maintain an informed status on Company issues related to corporate social responsibility," and "to monitor emerging issues potentially affecting the reputation of the . . . Company." (*Id.*, Annex 3 at vii.)

120. Strikingly, however, the 2007 Proxy Statement does not disclose that Pfizer's Board of Directors had received at least two reports during 2006 from its Chief Compliance Officer indicating that Pfizer was engaging in widespread violations of federal laws prohibiting the marketing of drugs for off-label uses. As set forth above, Pfizer's widespread violations involved numerous drugs and spanned several years. Pfizer's Chief Compliance Officer had

provided information detailing these abuses and the Company's numerous violations of federal health care and FDA law to the Board pursuant to Pfizer's requirements under its 2004 Corporate Integrity Agreement.

121. Even more striking is that the 2007 Proxy Statement omitted the crucial fact that after receiving these reports of Pfizer's widespread violations of federal law, the Board chose not to stop this ongoing illegal activity. Rather, the Board chose to approve of this conduct as part of Pfizer's business plan, or at the very least consciously chose to disregard this information in intentional dereliction of its duties of overseeing Pfizer's compliance with federal law.

122. This omitted information was particularly material to Pfizer shareholders because it would have demonstrated that Pfizer's incumbent directors did not meet Pfizer's stated criteria for Board membership. The 2007 Proxy Statement provides that the "criteria for Board membership include[s]" the requirement that Directors "adhere to the Company's Code of Business Conduct and Ethics for members of the Board of Directors." (2007 Proxy Statement at 13; *accord id.* at 14 ("The members of our Board of Directors are also required to comply with a Code of Business Conduct and Ethics.")) Pfizer's Code of Business Conduct for Directors specifically requires them to provide "oversight of ethics and compliance by employees of the Company." (*Id.* at 14.)

123. In particular, Paragraph 4 of the Code of Conduct for Pfizer Directors provides that "Directors must comply, and oversee compliance by employees, officers and other directors, with laws, rules and regulations applicable to the Company, including insider trading laws."

124. Thus, by choosing not to act upon reports of widespread violations of federal laws against off-label marketing, the Director Defendants both violated the terms of Pfizer's Code of Conduct, and fell short of Pfizer's published criteria necessary to qualify as a Pfizer

director. Accordingly, there can be little doubt that had Pfizer accurately disclosed its directors' approval of illegal conduct and/or conscious disregard of reports of widespread illegal marketing by Pfizer employees, its shareholders would likely have voted against reelecting those directors.

125. Similar false and misleading misstatements were made in the Company's 2007 Proxy Statement and again in Pfizer's Proxy Statements for 2008 and 2009. Pfizer's 2008 and 2009 Proxy Statements contained the same representations about Pfizer's Board of Directors as in the 2007 Proxy Statement. (2009 Proxy Statement at 5, 10-13, Annex 2 at iv, Annex 3 at vi-vii; 2008 Proxy Statement at 5, 10-13, Annex 2 at iv, Annex 3 at vi-vii.) Accordingly, Pfizer similarly misled its shareholders, causing them to vote for its incumbent directors in those years as well. In 2007 and 2008, Pfizer shareholders reelected all of Pfizer's directors, which included all of Pfizer's current directors except Stephen Sanger, who became director in place of William Holwell in February 2009. In 2009, Pfizer shareholders voted to reelect all of Pfizer's current directors.

126. In addition, the materially false and misleading statements and omissions in Pfizer's 2009 Proxy Statements that failed to disclose that the Director Defendants received numerous reports of Pfizer's widespread violation of federal laws prohibiting off-label marketing of pharmaceutical drugs caused Pfizer's shareholders to approve Pfizer's Restated Stock Plan. In the 2009 Proxy Statement, Pfizer's directors recommended that Pfizer shareholders approve the Restated Stock Plan, which would increase the amount of stock grants to be awarded to Pfizer employees and outside directors (*i.e.*, all except Messrs. Kindler and Steere) for as little as one year of positive performance. The Restated Stock Plan increased the potential stock grants to executives, outside directors and other employees by $425,000,000.

127. Pfizer's incumbent directors portrayed the Restated Stock Plan as necessary

increase in potential compensation to reward high-performing employees, officers and outside directors.

128. But had Pfizer disclosed to its shareholders that its employees, officers and even outside directors had been involved in or had knowledge of a Company-wide business plan to illegally market Pfizer drugs for off-label purposes, then Pfizer's shareholders would not have voted to approve the additional compensation in the Restated Stock Plan. Pfizer shareholders would have had little reason to increase the compensation of employees, officers and directors who participated in illegal marketing misconduct, and thereby reward them for their illegal activity. Rather, Pfizer's shareholders would have instead demanded that appropriate legal action be taken against those employees, officers and outside directors who participated in this widespread misconduct.

129. Accordingly, Pfizer's shareholders have been damaged by the materially false and misleading statements and omissions in the 2009 Proxy Statement that procured shareholders' approval for an increase in compensation for employees, officers and outside directors who had been involved in wide-ranging criminal conduct—a proposal that would have been rejected had the true facts been disclosed to shareholders.

VI. DEMAND ON THE BOARD OF DIRECTORS WOULD BE FUTILE

130. Plaintiff brings this action derivatively in the right and for the benefit of Pfizer to redress the breaches of fiduciary duty and other violations of law by Defendants as alleged herein. Plaintiff will adequately and fairly represent the interests of Pfizer and its shareholders in enforcing and prosecuting its rights. Plaintiff did not make a demand on the Pfizer Board prior to instituting this action to recover damages suffered by Pfizer because doing so would be futile.

131. None of the Directors-Defendants can properly consider demand. Among other things, the prior Corporate Integrity Agreements assured that the Board was regularly informed

(at least semi-annually) about Pfizer's compliance or non-compliance with various federal regulations relating to the sale of drugs to the public. The Board's actions, which amount to deliberately managing Pfizer to engage in criminal and otherwise unlawful business conduct cannot be considered a valid exercise of business judgment. Furthermore, a majority of the Board, including the nine Director Defendants who are either admittedly not independent (inside executives Kindler and Steere) or served on a Committee during the Relevant Period that imposed a heightened duty to identify and correct the misconduct alleged herein (Ausiello, Brown, Burns, Burt, Cornwell Gray and Horner) face a substantial likelihood of liability for their breaches of fiduciary duty. Demand as to these defendants is futile and therefore excused.

A. Pfizer's Directors Acted in Bad Faith, Without Exercising Business Judgment, In Approving Pfizer's Illegal Off-Label Marketing and Kickbacks

132. The Board currently consists of the following thirteen Director-Defendants: Dennis Ausiello, Michael Brown, Anthony Burns, Robert Burt, Don Cornwell, William Gray, Constance Horner, James Kilts, Jeffrey Kindler, George Lorch, Dana Mead, Suzanne Johnson, and William Steere.[16] As noted above in ¶¶109-15, each of the Director-Defendants knew that they had a duty to monitor and ensure Pfizer's compliance with FDA requirements, Federal healthcare program requirements and the Federal anti-kickback statute. Despite being informed of numerous red flags that numerous Pfizer employees did not comply with those statutes and were breaking the law by engaging in illegal sales and promotion practices, the Director-Defendants consciously disregarded their responsibility to act. This is particularly true for members of the Audit and Corporate Governance Committees.

133. The Pfizer Directors knowingly, in an intentional breach and/or conscious disregard of their fiduciary duties, either chose not to address the pervasive, rampant illegal

[16] Non-party Stephen Sanger became a director in February 2009.

conduct described herein, including the improper off-label activities and illegal sales practices used to promote at least 13 different Pfizer products in at least five of the Company's eight different pharmaceutical divisions (as delineated in the Company's SEC filings), or affirmatively approved, condoned and/or directed the illegal activities that subjected Pfizer to the largest government fine in history.

134. As described above, numerous facts establish that the Directors were regularly apprised of Pfizer's activities regarding the Company's compliance (or lack thereof) with applicable health regulations and potential violations of law, and received numerous "red flags" of this wrongdoing, as substantiated by the two prior Corporate Integrity Agreements that mandated regular and direct reporting of compliance issues to the Board, numerous settlements with health regulators that included some of the most significant fines for off-label marketing practices prior to Pfizer's most recent $2.3 billion settlement, as well as numerous *qui tam* actions. The numerous "red flags" received by the Board include, among others:

- Numerous internal reports by Pfizer's Chief Compliance Officer and dozens of Pfizer employees regarding ongoing, illegal marketing of the Company's most material and important products, including Lipitor, Viagra, Zyrtec, Norvasc, Zithromax, Zoloft, Glucotrol, Geodon, Bextra, Celebrax, Repax, Lyrica Zyvox and Genotropin. Under the terms of the 2002 and 2004 CIAs, these allegations monitored by the Company's Chief Compliance Officer—a position Defendant Kindler held during his term as General Counsel from 2002 through 2006—and reported directly to the Board of Directors;

- At least eleven *qui tam* lawsuits alleging improper and illegal marketing of Pfizer pharmaceuticals described above based on the very misconduct that was to be reported to the Board under the terms of the 2002 and 2004 CIAs;

- Numerous settlements covering criminal and civil misconduct and imposing some of the most significant fines in health care fraud prosecutions, including:

    - A $49 million settlement in 2002 to resolve civil claims that Pfizer failed to report best prices for its drug Lipitor as is required under the Medicaid Drug Rebate Statute;

    - A 2004 guilty plea and payment of $430 million to resolve criminal

charges and civil liability in connection with the Company's fraudulent marketing practices with respect to the drug Neurontin;

- A 2007 settlement in which Pfizer paid $34 million and pled guilty to paying kickbacks for formulary placement of its drugs and entered into a Deferred Prosecution Agreement for off-label distribution of the drug Genotropin;

- At least three FDA Violation Notices and one FDA Warning Letter—directly sent to the attention of Pfizer's CEO—informing the Company of precisely the same misconduct regarding misleading and/or otherwise improper marketing of Pfizer drugs Geodon, Zydon, Bextra, Celebrex that became the subject of Pfizer's record-setting $2.3 billion criminal fine and civil fraud settlement.. In addition, a 2008 FDA Warning Letter directly to Pfizer's Chairman and CEO Defendants Kindler about the illegal marketing of Viagra.

135. Accordingly, the Board Defendants' actions in directing, permitting, or otherwise failing to prevent the continued off-label marketing practices and other illegal conduct described herein, represents, at best, a sustained, systematic failure of the Board to exercise oversight based on its conscious disregard of these red flags (and, at worst, the Board's approval of a Pfizer business plan to increase short-term profit by illegally marketing its products), and demonstrates that a majority of the Defendants' did not act in good faith and/or that their conduct was not a valid exercise of business judgment. Accordingly, a prior demand that the Director Defendants commence this action is excused.

B. A Majority of the Pfizer Directors Face a Substantial Likelihood of Liability for Encouraging or Consciously Disregarding Pfizer's Widespread Illegal Conduct.

136. Due to their direction, approval, and conscious disregard of the pervasive illegal marketing activity complained of herein, and the numerous facts establishing the Directors' lack of good faith and breach of their fiduciary duties, a majority of the Pfizer directors face a substantial likelihood of liability and are thus disabled from properly considering demand. Because these directors face such substantial likelihood of liability, they cannot be considered disinterested and/or independent for purposes of satisfying demand futility.

137. The Board currently consists of the following fourteen (14) individuals: Defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, Sanger, and Steere—nine of whom (Brown, Burns, Burt, Cornwell, Gray, Horner, Lorch, Mead, and Steere) have served as directors since at least 2002 (the beginning of the period of wrongdoing alleged herein). Three other Defendants—Ausiello (director since 2006), Kilts (since 2007), Kindler (since 2006) and Johnson (since 2007)—joined the Board more recently, serving as directors during the period in which the 2004 CIA was in effect. Moreover, Kindler was the Company's General Counsel—personally responsible for implementation and compliance with the 2002 CIA and 2004 CIA—before becoming its Chief Executive and joining the Board.

138. All of these Directors were obligated to ensure Pfizer's compliance with the terms of the CIA and to exercise their valid business judgment in overseeing the Company and its affairs. Except for non-party Sanger, who only joined the Board in February of this year, each of these Directors was aware of, consciously disregarded and/or declined to correct Pfizer's ongoing illegal activities and faces a substantial likelihood of liability, and therefore cannot appropriately consider demand. Further, additional facts specific to the Defendants below—constituting a majority (nine of 14 members) of the Board—create additional infirmities based on conflicts of interest, divided loyalties, and/or a lack of independence, and further support the conclusion that demand with respect to these Defendants is excused.

Defendant Kindler

139. Defendant Kindler has served as Pfizer's CEO and as Chairman of the Board since July 2006, and as such, receives substantial monetary compensation and other valuable benefits, including over $33 million in compensation during the relevant period, and, by the

Board's own admission, lacks independence. Prior to becoming CEO of the Company, Defendant Kindler served as General Counsel of Pfizer from January 2002 through July 2006. During that time, Kindler directly participated in litigating, reviewing, recommending, approving, negotiating and/or otherwise advising the Company with respect to the DOJ action that resulted in a $340 million settlement resolving allegations relating to Pfizer's off-label promotion of Neurontin. Defendant Kindler was also involved in reviewing, negotiating and/or approving the terms of the 2004 CIAs, which placed significant obligations on the Company and its management to ensure compliance with all applicable health laws and provided for significant penalties. In fact, as General Counsel for Pfizer from 2002 through 2006 (prior to his elevation to CEO), Defendant Kindler, served as the Company's Chief Compliance Officer who was specifically obligated under the effective CIA to monitor the Company's "day-to-day" compliance with health care laws, FDA regulations and the terms of the CIA and to report to the Board on all pertinent compliance issues.

140. Given his prior role, Kindler knew that non-compliance could result in the possible exclusion of Pfizer from government health programs (an outcome that would effectively eliminate the Company's ability to conduct its business), and was intimately involved in the compliance matters at the heart of this action. Accordingly, Defendant Kindler is not disinterested, faces substantial liability for his misconduct and is incapable of impartially considering a demand to commence and vigorously prosecute this action.

Defendant Steere

141. Defendant Steere acted as CEO and Chairman of the Company for almost a decade, serving as Chairman from 1992 to April 2001 and as CEO from 1991 to 2000, and by the Board's own admission, lacks independence. Pursuant to Defendant Steere's service as CEO, he

has received substantial monetary compensation and other valuable benefits, totaling tens of millions of dollars, and continues to receive director fees of at least $275,000 per year as a Chairman Emeritus of the Company. As CEO in 2000, Defendant Steere had direct control over the Company's business operations and thus had the power to influence and control, and did influence and control, directly or indirectly, the decisionmaking of Pfizer. Thus, in accordance with the Board's own admission, Defendant Steere lacks independence, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action.

Audit Committee Defendants Burns, Burt, Cornwell, and Johnson

142. Defendants Burns, Burt, and Cornwell have each served as members of the Board of Directors since at least 2000 and also served as members of Pfizer's Audit Committee during the relevant period. Defendant Johnson has served as a member of Pfizer's Audit Committee since September 2007.

143. Specifically, Defendant Burns served on the Audit Committee from 2005 through 2008; Burt served as a member of the Audit Committee from 2001 through 2004 (including as its Chair during those years); as did Defendant Cornwell, who has served as a director since 1997 and as a member of the Audit Committee from at least 2001 through 2008 (including as its Chair in 2007 and 2008).

144. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee are charged with reviewing the Company's compliance with laws, regulations, and internal procedures, as well as the Company's "policies with respect to risk assessment and risk management, and review contingent liabilities and risks that may be material to the Company and major legislative and regulatory developments which could materially impact the Company's contingent liabilities and risks."

145. During their respective terms, the Audit Committee members met at least six times per year, and often much more frequently. In fact, following the 2004 CIA, the Audit Committee went from meeting six to seven times per year in 2001 through 2004, to meeting between 12 and 14 times per year in the period from 2005 from 2008.

146. Pursuant to the 2004 CIA and the Audit Committee Charter, the Audit Committee received regular reports regarding Pfizer's compliance (or lack thereof) with applicable health laws and regulations. The Audit Committee Defendants nevertheless violated their fiduciary duties to act in good faith to address the violations complained of herein. Accordingly, Defendants Burns, Burt and Cornwell face a substantial likelihood of liability and cannot appropriately consider demand, and therefore demand is excused with respect to these Defendants.

Corporate Governance Committee Defendants Ausiello, Brown, Gray and Horner

147. During the Relevant Period, four Director Defendants have served as members of the Corporate Governance Committee—Ausiello (member of committee since 2007), Brown (member of committee since at least 2001), Gray (member of committee since at least 2001), and Horner (member of committee since at least 2001, and Chair of committee from 2001 through 2003 and 2006 through 2008).

148. Pursuant to the Corporate Governance Committee Charter, the members of the Corporate Governance Committee are charged with reviewing matters of corporate governance and maintaining an informed status on Company issues related to corporate social responsibility and its "visibility as a global corporate citizen," and are required to "monitor emerging issues potentially affecting the reputation of the pharmaceutical industry and the Company."

149. The Corporate Governance Committee met between four and 10 times per year

during the Relevant Period, and, as discussed above, were regularly apprised by of the Company's illegal conduct during their terms as members of the Board of Directors. The additional obligations imposed upon these Defendants pursuant to their membership on the Corporate Governance Committee—which mandated heightened vigilance to matters affecting Pfizer's standing as a "global corporate citizen," including the potentially devastating effect the further violation of the CIA (or other health regulations) would have on the Company's reputation (indeed, Pfizer's very ability to continue operating as a business)—underscores the severity of their breach of fiduciary duties in failing to in good faith address the violations of law complained of herein.

150. Indeed, as Pfizer now has the reputation as the recipient of the largest government criminal fine ever imposed on a public company for any legal violation, these Defendants face a substantial likelihood of liability for the breach of fiduciary duties and any demand upon them is futile and therefore excused.

151. In sum, none of the Director Defendants can properly consider demand because of their conscious disregard of Pfizer's widespread legal violations and/or the Defendants' active participation, approval or acquiescence in the illegal conduct alleged herein cannot be considered a valid exercise of business judgment, and at least a majority of the Directors—including nine Director Defendants who are either admittedly not independent (Kindler and Steere) or served on a Committee during the Relevant Period that imposed a heightened duty to identify and correct the misconduct alleged herein (Ausiello, Brown, Burns, Burtm Cornwell Gray and Horner)—face a substantial likelihood of liability for their breaches of fiduciary duty, demand as to these Defendants is futile and therefore excused.

COUNT I

DERIVATIVE CLAIM FOR VIOLATIONS OF SECTION 14(a) OF THE EXCHANGE ACT AND RULE 14a-9 PROMULGATED THEREUNDER BASED UPON MATERIAL MISSTATEMENTS IN AND OMISSIONS FROM PFIZER'S 2007-2009 PROXY STATEMENTS

(Against Director Defendants)

152. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

153. The Director Defendants caused Pfizer to issue the 2006 through 2008 Proxy Statements to solicit shareholder votes for the election of directors.

154. As alleged in detail above, these Proxy Statements contained materially false and misleading statements and omissions, including the failure to disclose that:

a. Pfizer's incumbent director nominees in 2007 through 2009 all received semi-annual compliance reports demonstrating that Pfizer was engaging in widespread illegal marketing of drugs for off-label purposes, as required by Pfizer's Corporate Integrity Agreement;

b. Pfizer's incumbent director nominees in 2007 through 2009, after receiving reports of widespread illegal activity, chose not to act to prevent future misconduct, and in doing so either approved of such illegal conduct or consciously disregarded it;

c. Pfizer's incumbent directors in 2007 through 2009 failed to meet Pfizer's own stated criteria for appropriate Directors because they violated Pfizer's Code of Conduct and Ethics for Directors, which specifically required Pfizer's directors to oversee the compliance by employees with federal rules and regulations; and

d. Pfizer's employees, officers, and outside directors did not deserve any of the potential increased compensation provided for in the Restated Stock Plan proposed to Pfizer shareholders in the 2009 shareholders because they had a role in Pfizer's widespread illegal marketing of drugs for off-label purposes, and other illegal activity.

155. The misrepresentations and omissions in each Proxy Statement were material to shareholders in voting on each Proxy Statement. The Proxy Statements were an essential link in

Defendants' conscious disregard for Pfizer's known illegal sales and promotion practices, as disclosure to the shareholders of the truth would have brought an end to shareholders' endorsement of the Director Defendants as fiduciaries and termination of the Company's compensation policies.

156. The Board's failure to include these material facts in the 2007 through 2009 Proxy Statements rendered the Proxy Statements materially false and misleading, in violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder.

157. As a direct and proximate result of the issuance of false and misleading Proxy Statements, Pfizer's stockholders have suffered a direct and significant damage to their voting rights, and in particular their rights to vote for directors who are appropriately overseeing Pfizer's compliance with federal law and Pfizer's stated criteria for directors.

158. Further, as a direct and proximate result of the issuance of false and misleading Proxy Statements, Pfizer has been exposed to ongoing and additional damages in the form of Pfizer's settlement with the federal government for conduct occurring from 2007 onward for violations of federal law, damages and expenses from qui tam "whistleblower suits," numerous consumer class actions, and other lawsuits and government investigations.

159. In connection with the wrongful acts alleged under this Count, the Director Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, or the facilities of a national securities exchange.

COUNT II

DERIVATIVE CLAIM FOR BREACH OF FIDUCIARY DUTY FOR CAUSING THE COMPANY TO ENGAGE IN UNLAWFUL CONDUCT AND/OR CONSCIOUSLY DISREGARDING WIDESPREAD VIOLATIONS OF FEDERAL LAW

(Against All Defendants)

160. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

161. Defendants all owed and owe fiduciary duties to Pfizer and its shareholders. By reason of their fiduciary relationships, Defendants specifically owed and owe Pfizer the highest obligation of good faith and loyalty in the administration of the affairs of Pfizer, including the oversight of Pfizer's compliance with federal laws governing the marketing of pharmaceuticals. Moreover, the Defendants had a fiduciary obligation to abide by Pfizer's Corporate Integrity Agreements with the government and expressly agreed to abide by Pfizer's code of conduct requiring compliance with federal laws against improper promotion and sales practices for off-label use and dosages, and against improper payment of kickbacks to healthcare professionals to induce the prescription of Pfizer's drugs.

162. Defendants consciously violated their corporate responsibilities in at least the following ways:

a. Deciding not to act to stop and prevent Pfizer's illegal marketing of off-label uses and/or dosages of Bextra, Lyrica, Geodon, and Zyvox after receiving reports of such illegal activity and numerous red flags indicating such widespread illegality, and/or consciously disregarding such reports and activity;

b. Deciding not to act to stop and prevent Pfizer's illegal kickbacks to health professionals for prescribing at least nine other Pfizer drugs, including Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and/or consciously disregarding such reports and activity;

c. Approving and/or consciously disregarding Pfizer's business plan of marketing its drugs through the widespread illegal promotion of off-label uses and dosages and through illegal kickbacks to healthcare professionals in order to maximize Pfizer's short-term profit but at the expense of shareholder's long-term interests and Pfizer's reputation and goodwill.

163. As a direct and proximate result of Defendants' conscious failure to perform their fiduciary obligations, Pfizer has sustained significant damages, not only monetarily, but also to its corporate image and goodwill. Such damage has included:

a. The largest criminal fine ever imposed in history in any matter against Pfizer, $1.2 billion, for the illegal off-label marketing of Bextra, and a $105 million criminal forfeiture of Bextra proceeds, the guilty plea of Pharmacia to a felony violation of the FDCA, and Pfizer's agreement to a non-prosecution agreement subjecting it to severe restrictions and potential future sanctions;

b. The largest DOJ civil fraud settlement in the history of the United States, $1 billion, for the illegal off-label promotion of Bextra, Lyrica, Geodon, and Zyvox and for illegal kickbacks to healthcare professionals to prescribe Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec;

c. Damages and the costs of legal expenses to defend against 11 Qui Tam "Whistleblower" suits arising from current and former employees reporting Pfizer's widespread illegal conduct and asserting allegations against Pfizer;

d. Damages and the costs of legal expenses from numerous consumer fraud actions alleging deceptive and illegal marketing of Pfizer drugs covered by the settlement, including an $89 million charge the Company announced on October 17, 2008 to pay for the settlement of consumer fraud lawsuits regarding the illegal marketing of Bextra and Celebrex, and consumer fraud class actions such as *Caltieri v. Pfizer Inc., et al.*, Civil Action No. 09-11480-DPW, (D. Mass., filed September 4, 2009), which challenge the deceptive marketing of the 11 other Pfizer drugs illegally marketed as set forth hrein.

e. Damages and legal expenses Pfizer has had to pay to settle State consumer protection actions regarding the illegal marketing alleged herein, including the $33 million settlement Pfizer announced on September 2, 2009, with 42 States and the District of Columbia regarding the illegal marketing of Geodon.

f. Damages and the costs of legal expenses to defend against numerous product liability suits by patients and consumers harmed by Pfizer's improper marketing of its drugs for off-label uses and dosages, including a $745 million

charge Pfizer announced on October 17, 2008 to settle product liability claims by plaintiffs who suffered injuries after falling victim to deceptive marketing of Bextra and Celebrex;

g. Loss of Pfizer's market value due to its lost reputation and goodwill as a result of incurring the largest criminal fine in history, which has caused Pfizer's reputation to decline from leading pharmaceutical manufacturer to leading corporate criminal wrongdoer.

164. As a result of the misconduct alleged herein, Defendants are liable to the Company.

COUNT III

DERIVATIVE CLAIMS FOR BREACH OF FIDUCIARY DUTY
(Against the Executive Defendants)

165. Plaintiffs incorporate by reference and reallege each and every allegation contained above as though fully set forth herein.

166. By reason of their positions as fiduciaries of the Company, the Executive Defendants owed duties of good faith, loyalty, and truthful disclosure.

167. The Executive Defendants consciously violated and breached these duties by causing Pfizer to employ a business plan of artificially increasing sales by engaging in unlawful sales and promotion practices by numerous Pfizer employees for a prolonged period of time in violation of FDA requirements, Federal healthcare program requirements and/or the Federal anti-kickback statute.

168. The Executive Defendants authorized and implemented Pfizer policies and practices of encouraging the widespread illegal marketing and promotion of off-label uses and dosages of Pfizer drugs, as well as the payment of illegal kickbacks to healthcare professionals to induce the prescription of Pfizer's drugs.

169. As a direct and proximate result of the Executive Defendants' breaches of

fiduciary duty, the Company has sustained, and will continue to sustain, substantial harm, including the damages set forth in ¶163.

170. The Executive Defendants are liable to the Company as a result of the acts alleged herein.

COUNT IV
DERIVATIVE CLAIM FOR UNJUST ENRICHMENT
(Against All Defendants)

171. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though full set forth herein.

172. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense of and to the detriment of Pfizer.

173. Plaintiff, as shareholder and representative of Pfizer, seeks restitution, damages, an order of this Court disgorging all profits, benefits and other compensation obtained by these Defendants from their wrongful conduct and fiduciary breaches, and other relief for the Company, in an amount to be proven at trial.

RELIEF REQUESTED

WHEREFORE, Plaintiffs demand judgment as follows:

(a) Determining that this action is a proper derivative action maintainable under law and demand is excused;

(b) Against all Defendants and in favor of Pfizer the damages sustained by the Company as a result of Defendants' breaches of fiduciary and contractual duties;

(c) Awarding to Pfizer restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the Defendants during the Relevant Period;

(d) Directing Pfizer to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein;

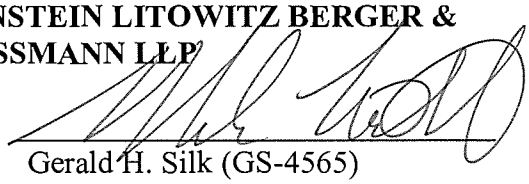
(e) Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

(f) Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP

By: 

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Additional Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA SHERIFFS' PENSION AND RELIEF FUND, derivatively, on behalf of PFIZER INC., Plaintiff, v. DENNIS A. AUSIELLO; MICHAEL S. BROWN; M. ANTHONY BURNS; ROBERT N. BURT, W. DON CORNWELL; WILLIAM H. GRAY III; CONSTANCE J. HORNER; JAMES M. KILTS; JEFFREY B. KINDLER; GEORGE A. LORCH; DANA G. MEAD; SUZANNE NORA JOHNSON; WILLIAM C. STEERE; JR.; DOUGLAS A. LANKLER; FRANK. A. D'AMELIO; IAN C. READ; and JOSEPH M. FECZKO; Defendants, and PFIZER INC., Nominal Defendant.	C.A. No. **ECF CASE** **VERIFIED DERIVATIVE COMPLAINT** **JURY TRIAL DEMANDED**

VERIFICATION

I, Osey McGee, Jr., verify that:

I am the Executive Director of Louisiana Sheriffs' Pension and Relief Fund ("Louisiana Sheriffs"), a plaintiff in the above action. I hereby verify that Louisiana Sheriffs has been a shareholder of Pfizer Inc. ("Pfizer") both before and during the period of misconduct complained of in the Verified Shareholder Derivative Complaint (the "Complaint"), and has continuously

held Pfizer common stock since such time, continues to hold such shares, and intends to continue to hold Pfizer shares until at least the resolution of this action. Additionally, I have reviewed the allegations made in the Complaint and to those of which I have personal knowledge I believe those allegations to be true. As to those allegations which I do not have personal knowledge, I rely on my counsel and their investigation and believe them to be true. Having received a copy of this Complaint and having reviewed it with my counsel, I hereby authorize its filing on behalf of Louisiana Sheriffs.

I declare that the foregoing is true and correct to the best of my knowledge.

Executed this 18 day of September, 2009 in Baton Rouge, Louisiana.

Osey McGee, Jr.
Executive Director
Louisiana Sheriffs' Pension and Relief Fund

JS 44C/SDNY
REV. 1/2008

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

FILED
09 SEP 18 PM 5:18
U.S. DISTRICT COURT
S.D.N.Y.

PLAINTIFFS
Louisiana Sheriffs' Pension and Relief Fund, derivatively, on behalf of Pfizer Inc.

DEFENDANTS Dennis A. Ausiello; Michael S. Brown; M. Anthony Burns; Robert N. Burt; W. Don Cornwell; William H. Gray III; Constance J. Horner; James M. Kilts; Jeffrey B. Kindler; George A. Lorch; Dana G. Mead; Suzanne Nora Johnson; William C. Steere, Jr.; Douglas M. Lankler; Frank A. D'Amelio; Ian C. Read; and Joseph M. Feczko. Pfizer Inc. (Nominal Defendant)

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Mark Lebovitch, Esq.
Bernstein Litowitz Berger & Grossmann LLP
1285 Ave. of the Americas, Floor 38
New York, NY 10019 (212) 554-1400

ATTORNEYS (IF KNOWN)

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)
(DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY) The shareholder derivative action alleges that the Board of Directors of nominal defendant Pfizer Inc. and other named defendants are liable for violations of the federal securities laws, Section 14(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78n, as well as for breaches of fiduciary duty and other causes, in connection with their conduct in causing or failing to prevent misconduct that has harmed Pfizer Inc.

Has this or a similar case been previously filed in SDNY at any time? No? ☐ Yes? ☒ Judge Previously Assigned Hon. Jed S. Rakoff

If yes, was this case Vol. ☐ Invol. ☐ Dismissed. No ☒ Yes ☐ If yes, give date _____ & Case No. _____

(PLACE AN [x] IN ONE BOX ONLY) NATURE OF SUIT

TORTS

CONTRACT
- [ ] 110 INSURANCE
- [ ] 120 MARINE
- [ ] 130 MILLER ACT
- [ ] 140 NEGOTIABLE INSTRUMENT
- [ ] 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- [ ] 151 MEDICARE ACT
- [ ] 152 RECOVERY OF DEFAULTED STUDENT LOANS (EXCL VETERANS)
- [ ] 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS
- [X] 160 STOCKHOLDERS SUITS
- [ ] 190 OTHER CONTRACT
- [ ] 195 CONTRACT PRODUCT LIABILITY
- [ ] 196 FRANCHISE

REAL PROPERTY
- [ ] 210 LAND CONDEMNATION
- [ ] 220 FORECLOSURE
- [ ] 230 RENT LEASE & EJECTMENT
- [ ] 240 TORTS TO LAND
- [ ] 245 TORT PRODUCT LIABILITY
- [ ] 290 ALL OTHER REAL PROPERTY

PERSONAL INJURY
- [ ] 310 AIRPLANE
- [ ] 315 AIRPLANE PRODUCT LIABILITY
- [ ] 320 ASSAULT, LIBEL & SLANDER
- [ ] 330 FEDERAL EMPLOYERS' LIABILITY
- [ ] 340 MARINE
- [ ] 345 MARINE PRODUCT LIABILITY
- [ ] 350 MOTOR VEHICLE
- [ ] 355 MOTOR VEHICLE PRODUCT LIABILITY
- [ ] 360 OTHER PERSONAL INJURY

ACTIONS UNDER STATUTES

CIVIL RIGHTS
- [ ] 441 VOTING
- [ ] 442 EMPLOYMENT
- [ ] 443 HOUSING/ ACCOMMODATIONS
- [ ] 444 WELFARE
- [ ] 445 AMERICANS WITH DISABILITIES - EMPLOYMENT
- [ ] 446 AMERICANS WITH DISABILITIES -OTHER
- [ ] 440 OTHER CIVIL RIGHTS

PERSONAL INJURY
- [ ] 362 PERSONAL INJURY - MED MALPRACTICE
- [ ] 365 PERSONAL INJURY PRODUCT LIABILITY
- [ ] 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

PERSONAL PROPERTY
- [ ] 370 OTHER FRAUD
- [ ] 371 TRUTH IN LENDING
- [ ] 380 OTHER PERSONAL PROPERTY DAMAGE
- [ ] 385 PROPERTY DAMAGE PRODUCT LIABILITY

PRISONER PETITIONS
- [ ] 510 MOTIONS TO VACATE SENTENCE 28 USC 2255
- [ ] 530 HABEAS CORPUS
- [ ] 535 DEATH PENALTY
- [ ] 540 MANDAMUS & OTHER
- [ ] 550 CIVIL RIGHTS
- [ ] 555 PRISON CONDITION

FORFEITURE/PENALTY
- [ ] 610 AGRICULTURE
- [ ] 620 OTHER FOOD & DRUG
- [ ] 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- [ ] 630 LIQUOR LAWS
- [ ] 640 RR & TRUCK
- [ ] 650 AIRLINE REGS
- [ ] 660 OCCUPATIONAL SAFETY/HEALTH
- [ ] 690 OTHER

LABOR
- [ ] 710 FAIR LABOR STANDARDS ACT
- [ ] 720 LABOR/MGMT RELATIONS
- [ ] 730 LABOR/MGMT REPORTING & DISCLOSURE ACT
- [ ] 740 RAILWAY LABOR ACT
- [ ] 790 OTHER LABOR LITIGATION
- [ ] 791 EMPL RET INC SECURITY ACT

IMMIGRATION
- [ ] 462 NATURALIZATION APPLICATION
- [ ] 463 HABEAS CORPUS-ALIEN DETAINEE
- [ ] 465 OTHER IMMIGRATION ACTIONS

ACTIONS UNDER STATUTES

BANKRUPTCY
- [ ] 422 APPEAL 28 USC 158
- [ ] 423 WITHDRAWAL 28 USC 157

PROPERTY RIGHTS
- [ ] 820 COPYRIGHTS
- [ ] 830 PATENT
- [ ] 840 TRADEMARK

SOCIAL SECURITY
- [ ] 861 HIA (1395ff)
- [ ] 862 BLACK LUNG (923)
- [ ] 863 DIWC/DIWW (405(g))
- [ ] 864 SSID TITLE XVI
- [ ] 865 RSI (405(g))

FEDERAL TAX SUITS
- [ ] 870 TAXES (U.S. Plaintiff or Defendant)
- [ ] 871 IRS-THIRD PARTY 26 USC 7609

OTHER STATUTES
- [ ] 400 STATE REAPPORTIONMENT
- [ ] 410 ANTITRUST
- [ ] 430 BANKS & BANKING
- [ ] 450 COMMERCE
- [ ] 460 DEPORTATION
- [ ] 470 RACKETEER INFLU-ENCED & CORRUPT ORGANIZATION ACT (RICO)
- [ ] 480 CONSUMER CREDIT
- [ ] 490 CABLE/SATELLITE TV
- [ ] 810 SELECTIVE SERVICE
- [ ] 850 SECURITIES/ COMMODITIES/ EXCHANGE
- [ ] 875 CUSTOMER CHALLENGE 12 USC 3410
- [ ] 890 OTHER STATUTORY ACTIONS
- [ ] 891 AGRICULTURAL ACTS
- [ ] 892 ECONOMIC STABILIZATION ACT
- [ ] 893 ENVIRONMENTAL MATTERS
- [ ] 894 ENERGY ALLOCATION ACT
- [ ] 895 FREEDOM OF INFORMATION ACT
- [ ] 900 APPEAL OF FEE DETERMINATION UNDER EQUAL ACCESS TO JUSTICE
- [ ] 950 CONSTITUTIONALITY OF STATE STATUTES

Check if demanded in complaint:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.? IF SO, STATE:

DEMAND $_____ OTHER _____ JUDGE Hon. Jed S. Rakoff DOCKET NUMBER 09-cv-7822-JSK

Check YES only if demanded in complaint
JURY DEMAND: ☒ YES ☐ NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.
See attached sheet

(PLACE AN x IN ONE BOX ONLY) **ORIGIN**

[x] 1 Original Proceeding [ ] 2a. Removed from State Court [ ] 3 Remanded from Appellate Court [ ] 4 Reinstated or Reopened [ ] 5 Transferred from (Specify District) [ ] 6 Multidistrict Litigation [ ] 7 Appeal to District Judge from Magistrate Judge Judgment

[ ] 2b. Removed from State Court **AND** at least one party is pro se.

(PLACE AN x IN ONE BOX ONLY) **BASIS OF JURISDICTION** ***IF DIVERSITY, INDICATE CITIZENSHIP BELOW. (28 USC 1322, 1441)***

[ ] 1 U.S. PLAINTIFF [ ] 2 U.S. DEFENDANT [X] 3 FEDERAL QUESTION (U.S. NOT A PARTY) [ ] 4 DIVERSITY

CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

	PTF	DEF		PTF	DEF		PTF	DEF
CITIZEN OF THIS STATE	[ ] 1	[ ] 1	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	[ ] 3	[ ] 3	INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	[ ] 5	[ ] 5
CITIZEN OF ANOTHER STATE	[ ] 2	[ ] 2	INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE	[ ] 4	[ ] 4	FOREIGN NATION	[ ] 6	[ ] 6

PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

Louisiana Sheriffs Pension and Relief Fund
1225 Nicholson Drive
Baton Rouge, LA 70802-7537
(225) 219-0500
Parish of East Baton Rouge, Louisiana

DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

See Attached Rider

DEFENDANT(S) ADDRESS UNKNOWN
REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: [ ] WHITE PLAINS [X] MANHATTAN
(DO NOT check either box if this a PRISONER PETITION.)

DATE September 18, 2009
RECEIPT #

SIGNATURE OF ATTORNEY OF RECORD

ADMITTED TO PRACTICE IN THIS DISTRICT
[ ] NO
[x] YES (DATE ADMITTED Mo. Sept. Yr. 2000)
Attorney Bar Code # ML-6654

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge _____ is so Designated.

J. Michael McMahon, Clerk of Court by _____ Deputy Clerk, DATED _____.

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

EXPLANATION OF WHY CASES ARE DEEMED RELATED

The action alleges that the Board of Directors of nominal defendant Pfizer Inc. and other named defendants are liable for violations of the federal securities laws, breaches of fiduciary duty and other causes in connection with their conduct in causing or failing to prevent misconduct that has harmed Pfizer Inc. The complaint arises from similar conduct by many of the same defendants, and will involve many of the same exhibits and witnesses, as those in *Klein v. Ausiello*, 09-cv-7822, which is currently pending before the Honorable Jed S. Rakoff.